The University of Liverpool

Doctorate in Clinical Psychology

Emotional Distress in People with Traumatic Brain Injury (TBI): Exploring Psychological Processes

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June 2018

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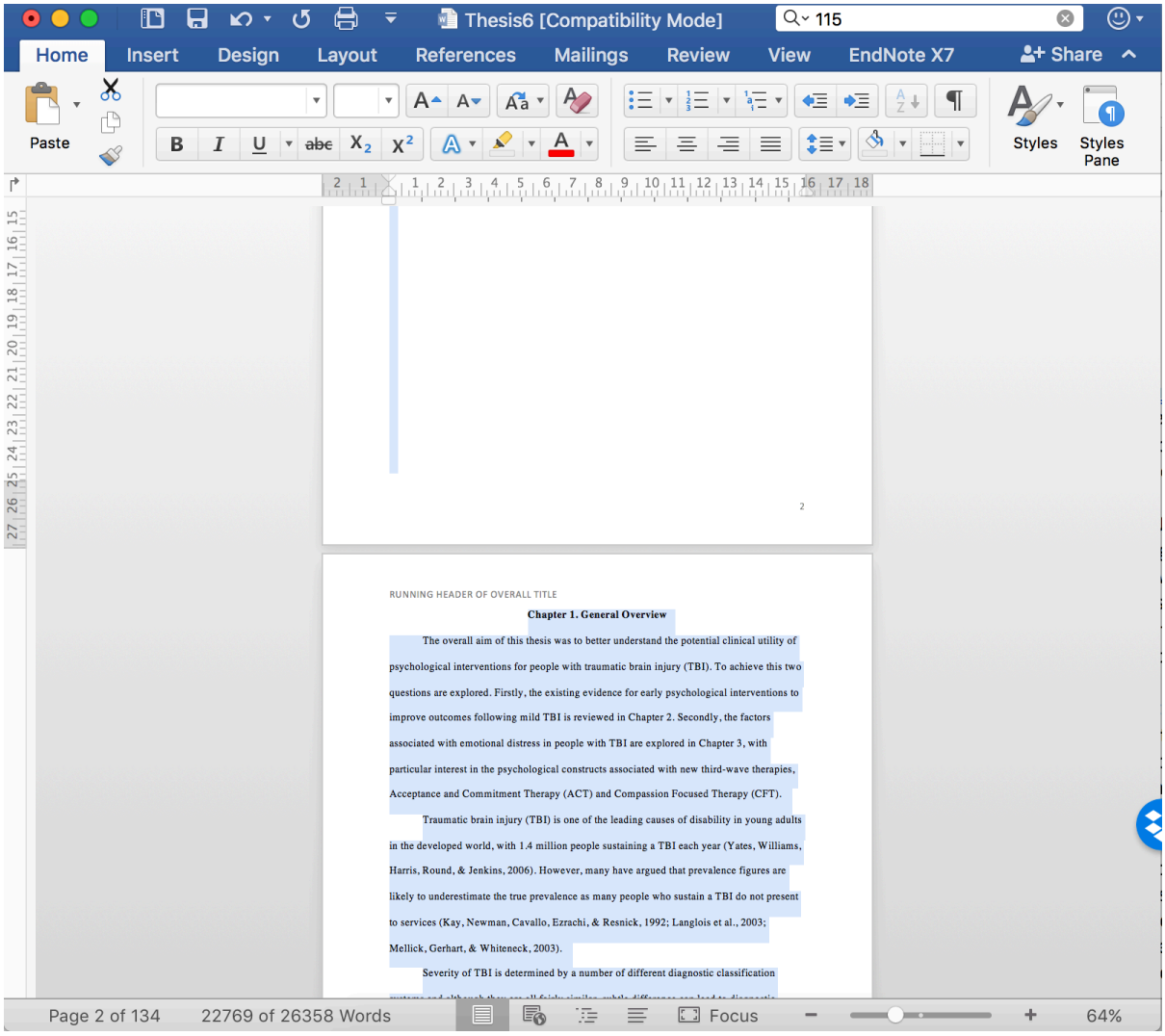
Submitted in partial fulfilment of the degree of Doctorate in Clinical Psychology at the Division of Clinical Psychology, School of Psychology, University of Liverpool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Chapter 1. General Overview
The overall aim of this thesis was to better understand the potential clinical utility of psychological interventions for people with traumatic brain injury (TBI). To achieve this two questions are explored. Firstly, the existing evidence for early psychological interventions to improve outcomes following mild TBI is reviewed in Chapter 2. Secondly, the factors associated with emotional distress in people with TBI are explored in Chapter 3, with particular interest in the psychological constructs associated with new third-wave therapies, Acceptance and Commitment Therapy (ACT) and Compassion Focused Therapy (CFT).
Traumatic brain injury (TBI) is one of the leading causes of disability in young adults in the developed world, with 1.4 million people sustaining a TBI each year (Yates, Williams, Harris, Round, & Jenkins, 2006). However, many have argued that prevalence figures are likely to underestimate the true prevalence as many people who sustain a TBI do not present to services (Kay, Newman, Cavallo, Ezrachi, & Resnick, 1992; Langlois et al., 2003; Mellick, Gerhart, & Whiteneck, 2003).
Severity of TBI is determined by a number of different diagnostic classification
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Acknowledgements

There are a number of people I would like to thank for supporting me throughout the process of completing my thesis. Firstly, to those who gave their time and participated in this study I thank you for allowing this and other research to be completed. Without those willing to generously volunteer their time, such research including the present project, would not be possible. I would also like to thank the Liverpool Expert by Experience group and Headway UK, within which members kindly volunteered their time to review and provide comments regarding the design of the present project. Additionally, I would like to thank the local Headway groups who allowed me to attend their groups and participate in activities. The conversations I had and the enthusiasm the project was met with further highlighted the importance of the present review and gave me additional motivation to persevere throughout this process.

Secondly, I would like to thank my supervisors Dr Perry Moore and Dr Ross White for their ongoing support and guidance. Their patience, positivity and constructive feedback have been invaluable. Additionally, I would like to thank Dr Luna Centifanti for reviewing my statistical analysis, providing feedback and supporting me in ensuring the analyses completed in the present project were robust.

Thirdly, I would like to thank my friends and family for their ongoing support throughout the three years and for providing much welcome breaks from work. A special thank you to my wonderful cohort, who have always been there to motivate me when things got tough or just providing a listening ear when needing to think things through. I feel truly fortunate to have had the pleasure of sharing this experience with you all.

Finally, (and perhaps most oddly) I would like to thank my dog, Kgosi, who has been my constant companion and sat with me whilst I wrote the majority of this thesis.

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Chapter 1. General Overview

The overall aim of this thesis was to better understand the potential clinical utility of psychological interventions for people with traumatic brain injury (TBI). To achieve this two questions are explored. Firstly, is there evidence for the clinical utility of early psychological therapies to improve outcomes following mild TBI. The evidence for this is reviewed in Chapter 2. Secondly, the factors associated with emotional distress in people with TBI are explored in Chapter 3, with particular interest in the psychological constructs associated with new third-wave therapies, Acceptance and Commitment Therapy (ACT) and Compassion Focused Therapy (CFT).

Traumatic brain injury (TBI) is one of the leading causes of disability in young adults in the developed world; it is estimated that approximately 1.4 million people attending emergency departments having sustained a head injury (National Institute for Clinical Excellence, 2013). However, many have argued that prevalence figures are likely to underestimate the true prevalence as many people who sustain a TBI do not present to services (Kay, Newman, Cavallo, Ezrachi, & Resnick, 1992; Langlois et al., 2003; Mellick, Gerhart, & Whiteneck, 2003).

Severity of TBI is determined by a number of different diagnostic classification systems and although they are all fairly similar, subtle differences can lead to diagnostic disagreements (Ruff et al., 2009). Most diagnostic criteria include scores deriving from the Glasgow Coma Scale (GCS), duration of loss of consciousness and duration of post-traumatic amnesia (PTA) as severity markers. The GCS is a neurological scale including observations of eye, verbal and motor responses to assess level of consciousness; scores range from 3-15, with a score of 3-8 indicating severe TBI, 9-12 indicating moderate TBI and 13-15 indicating mild TBI (American Congress of Rehabilitation Medicine Mild Traumatic Brain Injury Committee of the Head Injury Interdisciplinary Special Interest Group, 1993; Department of

Defense and Department of Veterans Affairs, 2008). Similarly, loss of consciousness for up to 30 minutes indicates a mild TBI, from 30 minutes to 24 hour indicates a moderate TBI and over 24 hours indicates a severe TBI. Finally, PTA is the disorientated state, which often follows TBI and is characterised by an inability to form new memories from day to day (Brooks, 1984). PTA lasting under one day indicates a mild TBI, one to seven days indicates a moderate TBI and over seven days indicates a severe TBI. However, it is common for people to fall within different categories according to different markers, for example a person with a GCS of 15 and a reported loss of consciousness of 15 minutes. Therefore, the diagnostic criteria are often used as a guide for clinicians, rather than definitive markers of injury.

Approximately 70-90% of TBIs are classified as being mild (Cassidy et al., 2004; Shukla & Devi, 2010). The majority of people who sustain a mild TBI are expected to make a full recovery with little or no intervention (Hall, Hall, & Chapman, 2005). However, there are a minority of people who continue to experience symptoms (including headache, nausea and cognitive complaints) for prolonged periods (Ruff et al., 1996). Whether these symptom complaints are due to impairments caused directly by the TBI or indirectly by psychological processes remains widely debated (Pertab, James, & Bigler, 2009; Rohling, Larrabee, & Millis, 2012). Regardless of the underlying cause, there remains a proportion of people who have sustained a mild TBI who continue to report symptoms that are considered disproportionate to their injury (Emanuelson, Andersson Holmkvist, Björklund, & Stålhammar, 2003).

Symptoms which persisted beyond three months following mild TBI have historically been termed post-concussion syndrome or post-concussion disorder (Mittenberg & Strauman, 2000). Whilst diagnostic criteria for post-concussion syndrome was present in the DSM-IV (American Psychiatric Association, 1994), it has since been incorporated into the diagnostic criteria for neurocognitive disorder in the DSM-V (American Psychiatric Association, 2013).

This has presented a challenge to clinicians and researchers working in this area as there appears no certain terminology regarding the presentation of persistent post-concussion symptoms following mTBI in new diagnostic manuals. Recent literature often terms these difficulties as 'persistent post-concussion symptoms' (PPCS; Moore, Mawdsley, Jackson & Atherton, 2017).

People who sustain a TBI are at greater risk of developing comorbid psychological difficulties (Fann et al., 2004; Hoge et al., 2008; Rosenthal, Christensen, & Ross, 1998); the most common psychological difficulties following TBI include depression and anxiety (Koponen et al., 2002). However, it has been suggested that psychological difficulties and PPCS may overlap in terms of their phenomenology. Iverson (2006) reported that many people with a diagnosis of depression, without a history of TBI, endorsed significant levels of post-concussion symptoms and argues that many people with mTBI who received a diagnosis of post-concussion syndrome may have been experiencing depression. Furthermore, Broshek, De Marco, and Freeman (2015) suggested that treating psychological factors following TBI may prevent or reduce the duration of post-concussion symptoms.

The first aim of the present thesis was to examine the existing evidence for early psychological interventions to prevent the development of PPCS. Therefore, Chapter 2 systematically reviews current evidence from randomised controlled trials (RCT) exploring the evidence for whether early psychological interventions following mild TBI are effective in preventing the development of PPCS. People presenting with PPCS following a mild TBI often represent an area of unmet clinical need. At present, these people appear to 'slip through the net', with a lack of specialist expertise within conventional psychology services. As the mechanisms underlying PPCS remain unclear, people presenting with such difficulties may be referred to several different professions including, Clinical Psychologists, Neuropsychologists, Neurologists and Consultants in Rehabilitation Medicine. As such the review presented in Chapter 2, will be of interest to a wide range of professions. Furthermore,

it is hoped that the findings of the review will aid the development of services for people presenting with persistent post-concussion symptoms.

Secondly, the present thesis aims to explore the extent to which psychological processes predict emotional distress, after controlling for demographic and injury-related factors. More specifically, the study presented in Chapter two explores the contribution of self-criticism, self-reassurance and psychological flexibility to emotional distress in people with TBI. These processes are considered central to the models underpinning third wave therapies Compassion Focused Therapy (CFT; Gilbert, 2000) and Acceptance and Commitment Therapy (ACT; Hayes, 2004). Unlike traditional Cognitive Behavioural Therapy (CBT) approaches, CFT and ACT do not try to challenge the content of negative thoughts, but rather focuses on the relationship one has with these thoughts. CFT achieves this through development of the self-soothing system, encouraging individuals to be kind and nurturing to the self, as opposed to being self-critical. Similarly, psychological flexibility refers to how flexible one can be around negative thoughts and allowing the self to be present and non-judgemental to pursue behaviours in line with valued goals, even in the presence of potentially debilitating negative thoughts (Hayes, Luoma, Bond, Masuda, & Lillis, 2006).

The primary reason for testing these constructs in relation to emotional distress was to assess the potential clinical utility of these third wave approaches. Exploring new therapeutic approaches is important for many reasons. Firstly, therapies are constantly evolving and exploring the utility of such approaches, not only provides more options for people needing such support but also allows for the refinement of existing approaches to ensure support is effective and appropriate. Secondly, evidence for traditional CBT for people with TBI, which remains the dominant approach, is limited with only two RCTs being reported in a recent review (Gertler, Tate, & Cameron, 2012). These studies yielded mixed results with one study (Fann et al., 2015) reporting results in favour of a CBT intervention compared with a control and one study (Simpson, Tate, Whiting, & Cotter, 2011) favouring the control group.

CFT and ACT may offer advantages over traditional CBT in that they focus on process, rather than content. Interest in process-based CBTs is continuing to grow with the advantages of such approaches over more traditional approaches being demonstrated in many clinical populations (Hayes & Hofmann, 2017). Whilst in traditional CBT approaches, the content of negative thoughts is challenged and evidence-based alternatives are developed (Wells & Matthews, 1994), CFT and ACT focuses on the context and the relationship one has with these thoughts to promote clinical change. Therefore, in instances where the content of such thoughts is not irrational or invalid, challenging this would not be appropriate. It is likely that in people who have sustained a TBI, there will be occasions when negative thoughts would not be irrational with some people being unable to return to their old work due to physical or cognitive impairments.

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Chapter 2: Psychological Interventions for the Prevention of Persistent Post-Concussion Symptoms Following Traumatic Brain Injury: A Systematic Review

Abstract

Persistent post-concussion symptoms (PPCS) present a significant challenge to professionals in neurotrauma and neurorehabilitation settings. It has been suggested that early psychological intervention is important for reducing and preventing post-concussion symptoms (PPCS). As such, the present review aimed to identify and evaluate the evidence for early psychological interventions for preventing PPCS. An electronic search of Medline, PsycINFO and SCOPUS was carried out to identify papers meeting the following eligibility criteria: (1) randomised controlled trials, (2) adult samples, (3) psychological interventions delivered within the first month following TBI, (4) validated outcome measures of post-concussion symptoms reported at follow-up. A total of nine studies reported in 12 papers met criteria and were included. While there is promising evidence for early psychological interventions for preventing PPCS, current findings are limited by the use of diverse methodologies, limited sample sizes and heterogeneity in effect sizes. Largest effect sizes were observed for CBT interventions, particularly when recruitment was focused on those at greatest risk of developing PPCS, and the intervention was delivered by Clinical Psychologists with further specialist training in neuropsychology. Future research could usefully focus on refining the identification of those considered at risk of developing PPCS and further evaluate psychological interventions in high quality studies.

Background

It is estimated that approximately 1.4 million people sustain a traumatic brain injury (TBI) each year[1] and this is continuing to rise[2]. Approximately 70% to 90% of these cases will be considered 'mild'[3]. There are many diagnostic criteria which may be used to determine TBI

severity. Mild TBI (mTBI) is often determined by a loss of consciousness of under 30 minutes, a duration of PTA of under 24 hours and a Glasgow Coma Scale of 13-15[4,5].

It is common for people to experience a constellation of physical, cognitive and psychological symptoms following mTBI, which are often termed post-concussion symptoms[6] (PCS). In most cases of mTBI, early symptoms, such as headaches and memory difficulties, are temporary and will resolve within three months with little or no intervention[7]. However, it has been well documented that there are a minority of people who experience persistent symptoms following mTBI; it is estimated that between 15-20% of people will continue to experience symptoms beyond three months[8].

It has long been debated as to whether the underlying mechanisms for PCS are driven predominantly by factors directly related to damage to the brain (organic) or indirect, possibly psychological factors (non-organic). The dominant theory was originally that PCS in the early stages were driven by organic factors, with non-organic secondary factors influencing the persistence of PCS[9]. However, more recently it has been argued that both organic and non-organic factors play a causal role in both early and persistent PCS[10]. Debates aside, it is widely reported that for some people who have sustained a MTBI, their symptom severity and duration is considered disproportionate to their physical injury but has a considerable impact on their quality of life[11].

There has been much research exploring what factors may predict the development of persistent post-concussion symptoms (PPCS). Psychological factors (both pre- and post-injury) [12] and neurological factors such as previous incidence of TBI[13] have been highlighted as positively predicting PPCS. Additionally, those who report PCS within two weeks of injury are at an elevated risk of PPCS at three months[10,12,14]. A recent systematic review found little support for multivariable prognostic models for PPCS, but reported that pre-injury

mental health, acute neuropsychological functioning, gender and post-injury anxiety were amongst the strongest independent predictors of persistent PPCS[15].

The importance of psychological intervention for people following mTBI has been highlighted throughout literature[16-18]. It has been postulated that cognitive biases, misattribution of symptoms and negative expectations influence reporting of PPCS and that addressing these factors early may be effective in alleviating these early symptoms and preventing development of other PPCS[16,19]. Therefore, recommendations for psychological interventions have emphasised the importance of reattributing symptoms to benign causes, rather than being a direct result of brain injury[20,21].

In a previous review, Mittenberg and colleagues[22] found that providing early psychological interventions was effective in reducing the frequency of PPCS in people who had sustained a MTBI. The interventions reviewed typically involved education, reassurance and reattribution of symptoms. The effect sizes that were reported ranged from 0.22 to 0.37 in favour of psychological interventions compared with control conditions. However, there were a number of limitations to this review. Firstly, methodological design and quality of included studies varied, with only two of nine included studies being randomised controlled trials (RCTs). Furthermore, the review included studies which reported PPCS as assessed by non-standardised measures and therefore the reliability and validity of such outcomes is unclear.

It could be argued that preventative approaches may be more effective as the misattribution of symptoms to a direct consequence of brain injury and negative biases associated with this are less developed and therefore potentially more amenable to change.

The present review aimed to conduct an up to date exploration of research that has investigated early psychological interventions to prevent persistent post-concussion symptoms. Specifically, the present review will examine what approaches to psychological interventions have been explored and evaluate the efficacy of such approaches considering

the quality and consistency of findings across published research. It is hoped that this will provide valuable information to guide future research and the further development of services for people following mTBI.

Method

Protocol and Registration

This review adhered to the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines (Appendix U). The review protocol has also been registered on PROSPERO (registration number CRD42018090818).

Eligibility Criteria

Types of Studies

Only randomised controlled trials (RCTs), cluster-randomised controlled trials and quasi-randomised controlled trials were eligible for inclusion. Observational, cross-sectional and case study designs were not included in the present review.

Types of Participants

Studies including adult (over 16 years old) samples who received an early psychological intervention within one month of sustaining a mild and moderate TBI were eligible for inclusion. Severity of injury could be author defined or was determined in accordance with Department of Defense and Department of Veterans Affairs[4] criteria.

Studies recruiting specifically participants with other neurological or psychiatric diagnoses, such as Dementia, Stroke, Parkinson's Disease or Major Depressive Disorder were excluded as it could be argued that there may be different underlying mechanisms maintaining reported symptoms.

Studies reporting a mixed sample of participants were included if 80% of participants met inclusion criteria.

Types of Intervention

For the purpose of this review, psychological interventions were defined as non-pharmacological interventions that aim to promote emotional wellbeing, reduce distress and were based on psychological theory and practice. These interventions included, but were not limited to, psycho-educational programmes, cognitive strategies training, counselling, cognitive behavioural therapy and guided self-help. As the present review is focused on preventative interventions, only studies reporting interventions which were delivered within the first month following injury were included.

Only studies reporting post-intervention data for the primary outcome were eligible for inclusion.

Types of Outcome

Primary Outcomes:

- Validated measures of PCS (for example, Rivermead Post-Concussion Questionnaire[23]; RPQ).

Secondary Outcomes:

- Validated measures of quality of life.
- Validated measures of depression symptoms, such as Beck Depression Inventory – *second edition*[24] (BDI-II) and the Hospital Anxiety and Depression Scale[25] (HADS)
- Validated measures of anxiety symptoms, such as Beck Anxiety Inventory[26] (BAI) and the HADS.

- Validated measures of self-reported cognitive symptoms such as the Everyday Memory Questionnaire[27] (EMQ)
- Attrition rates

Search Strategy

The following electronic databases were searched based on the search strategy in Appendix C.

- Medline (22/02/2018)
- PsycInfo (22/02/2018)
- Scopus (22/02/2018)

In addition, forward and backward referencing was completed on all included studies to identify further potentially eligible studies.

Selection of Studies

One rater (CJ) screened all titles and abstracts of studies identified by the electronic search results and irrelevant articles were excluded. Full texts for the remaining studies were obtained and reviewed for inclusion. Studies not meeting the inclusion criteria were excluded and a final list of studies for inclusion was achieved. In addition, 10% of studies at each stage were screened by a second rater (JO'B) who was blinded to the outcomes following screening by the first rater (CJ). Results were cross-checked and any disagreements were discussed and resolved and where necessary the opinion of the supervisory team (PM, RW) was sought.

Data Extraction and Management

Two raters (CJ, JO'B) independently completed data extraction and results were cross-checked. Disagreements were discussed and where necessary the opinion of the supervisory team (RW, PM) was sought.

Pre-prepared data extraction forms (Appendix D) were used to identify relevant information from the included manuscripts. The following data was extracted:

- Study data: author, year, design, setting, and country;
- Participant data: total sample size, number of participants allocated to each group, inclusion criteria, age, gender, nature of injury, percentage of sample reporting previous TBI and time since injury;
- Methodological data: duration of study, sequence generation, allocation concealment, method of blinding, any other concerns about bias;
- Intervention data: type of intervention, duration of intervention, type of control, duration of control;
- Outcome data: types of outcomes assessed, name and definitions of measures used, units of measurements, summary data for intervention and control groups (means and standard deviations).

Risk of Bias and Quality Assessment

Two raters (CJ, JO'B) independently assessed risk of bias using the Cochrane Risk of Bias Tool for randomised control trials which assesses randomisation, allocation concealment, blinding, incomplete outcome data, selective reporting and other bias[28]. Blinding participants to whether they received a psychological intervention or not is often not possible. For this reason, blinding of participants was not included in the risk of bias assessment for the present review. The same raters also independently assessed the overall quality of the evidence using the Grading Recommendation, Assessment, Development and Evaluations (GRADE) approach[29]. In this process, RCTs begin as high quality and then may be downgraded according to five factors: risk of bias, inconsistency, indirectness, imprecision and publication bias. Disagreements in this process were discussed and resolved and where necessary the opinion of a member of the supervisory team (PM) was sought.

In order to best assess the risk of reporting bias, authors of included studies were contacted to request a study protocol. However, as some studies were almost 20 years old, protocols were not always available.

Synthesis of Results

Due to the substantial clinical and methodological heterogeneity, particularly between interventions reported in included studies, meta-analysis was deemed inappropriate. Therefore, a narrative synthesis of the available evidence is provided.

Results

Results of the Searches

The electronic searches identified 9944 records. Ten additional records were found via the other search strategies. After duplicates were removed, 8583 records remained. Following title and abstract screening, 8543 records were removed due to irrelevance. Therefore, 40 full text papers were reviewed and nine studies reported in 12 papers met inclusion criteria and were included in the present review.

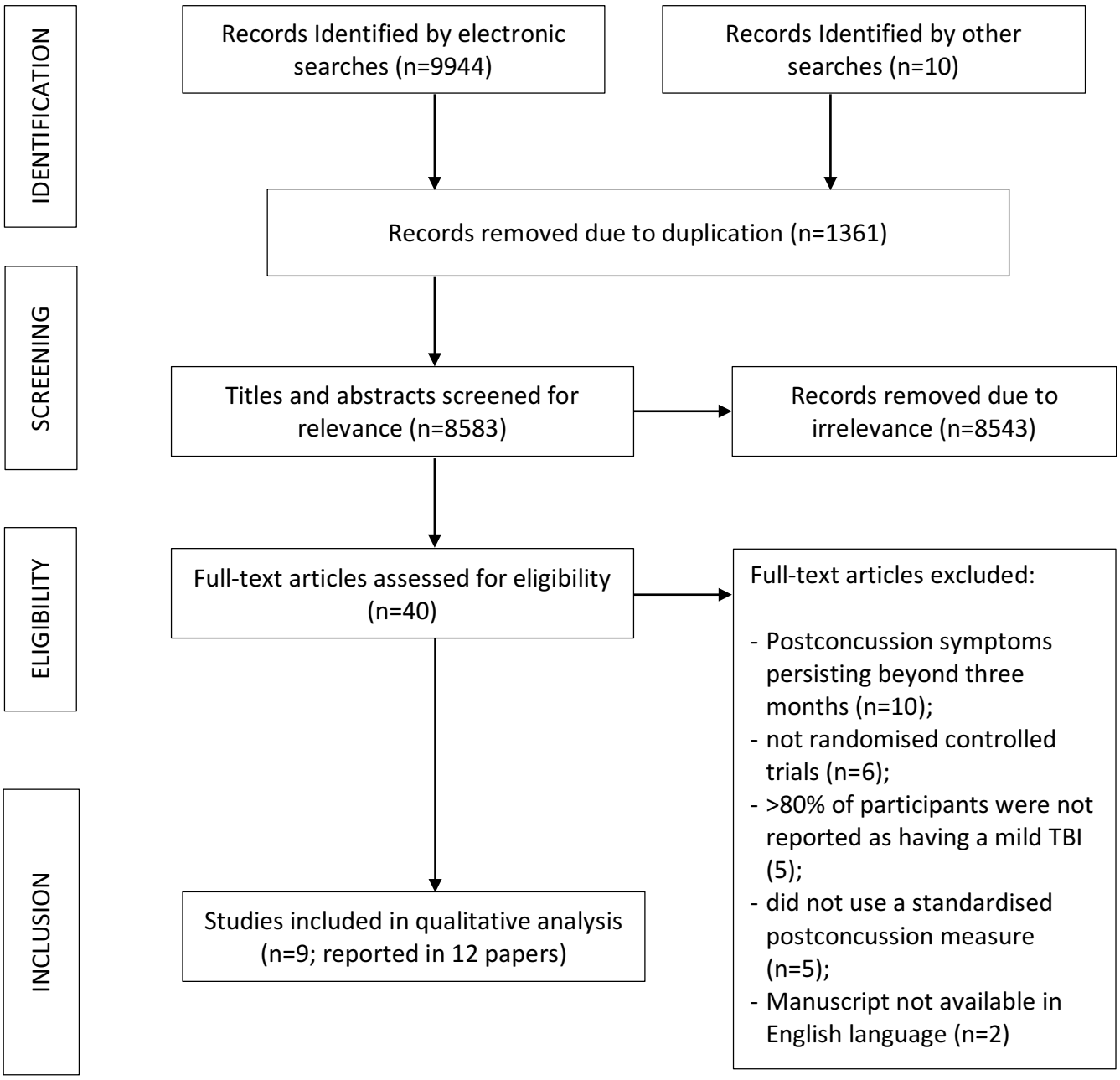

FIG. I. PRISMA diagram of study selection for inclusion in the present review.

Sample Characteristics of Included Studies

Nine studies[30-38] reported data from 1,695 participants from a variety of countries and settings. Characteristics of studies are detailed in Table 1.

Table 1. Summary of Sample Characteristics

Study	Country	Sample Size	Demographic Characteristics		Clinical Characteristics				
			Age (Mean, SD)	Gender (% male)	Severity of Injury (%)	Time Since Injury	Screened for Risk	Previous TBI (%)	Psychiatric History (%)
Andersson 2007[30]	Sweden	395	33 (12.57)	63	Mild: 97.0 Moderate: 0 Severe: 0 Unknown: 3.0	Two to eight weeks	Yes	Excluded	Not reported – ongoing excluded
Ghaffar 2006[31]	Canada	191	32 (11.5778)	64.9	Mild: 100 Moderate: 0 Severe: 0 Unknown: 0	Within one week	No	30.4	Not reported – ongoing excluded
Matuseviciene 2013[32]	Sweden	97	39.25 (SDs not reported)	39	Mild: 100 Moderate: 0 Severe: 0 Unknown: 0	10 days	No	Excluded	Not reported – ongoing excluded

Mittenberg 1996[33]	USA	58	46.35 (19.38)	68.95	Mild: 100 Moderate: 0 Severe: 0 Unknown: 0	Prior to discharge	No	Not reported	Not reported
Scheenen 2017[34]	Holland	91	40.9 (14.9)	54.55	Mild: 100 Moderate: 0 Severe: 0 Unknown: 0	Two weeks	Yes	Not reported	11.8
Silverberg 2013[35]	Canada	28	38.95 (12.04)	39	Mild: 100 Moderate: 0 Severe: 0 Unknown: 0	23.13 (7.0) days Mean (SD)	Yes	22.0	53.55
Suffoletto 2013[36]	USA	43	29.5 (8.81)	46.5*2	Mild: 100 Moderate: 0 Severe: 0 Unknown: 0	Prior to discharge	No	Not reported	Not reported

Wade 1997[37]	UK	314	39.99 (13.33)	74.6	Mild: 86.0 Moderate: 3.8 Severe: 2.1 Unknown: 8.1	10 days, or as soon as possible after notification	No	Not reported	Not reported
Wade 1998[38]	UK	478	31 (14.98)	61.5	Mild: 64.0 Moderate: 17.4 Severe: 7.8 Unknown: 10.1	10 days, or as soon as possible after notification	No	Not reported	Not reported

*1 Participants were recruited and randomly allocated to either the intervention or control condition from consecutive referrals. Only those in the intervention group who were reporting PCS received the intervention. All participants from the intervention condition were entered into the analysis regardless of whether they had received the intervention or not.

The sample sizes of included studies ranged from 28[35] to 478[38]. The mean age of participants reported in the included studies ranged from 29.5 years[36] to 46.35 years[33]. The proportion of males in included studies ranged from 39%[32,35] to 74.6%[37]. Two studies included a small proportion (2.1-7.8%) of participants with severe TBIs[37,38]. The time since injury prior to commencement of intervention ranged from less than one day (prior to discharge)[33,36] to eight weeks (although this was the maximum of a range of 2-8weeks)[30].

There was variability in whether people with a history of TBI were included and accounted for in sample data, with two studies[31,35] reporting the percentage of people reporting history or TBI and two studies[30,32]reported that people with a history of previous TBIs were specifically excluded. Similarly, only two studies[34,35] reported on the presence of psychiatric history with percentage of participants reported to have a psychiatric history varying across these studies.

Studies that did not specifically recruit people who had sustained a MTBI and were considered at risk of developing PPCS, recruited from consecutive presentations to hospital services. Three studies[30,34,35]indicated that a screening process to identify people at risk of developing PPCS was carried out. Two studies[34,35] reported that this was done prior to recruiting participants to the study and therefore all participants considered at risk of PPCS. One study[34] reported that people presenting with three or more PCS were considered at risk whilst one study[35] reported only one PCS was necessary to be considered at risk. However, one study[30] reported that participants were recruited from consecutive hospital presentations, but that only participants in the intervention group who were reporting symptoms of PCS received the intervention. In this study, all participants from the intervention group were entered into the analysis, regardless of whether they had received an intervention. It was indicated that 32.3% of participants included in the analysis within the intervention arm had not been offered the intervention.

In terms of diagnostic classifications used, five studies[30,31,34-36] used the Mild Traumatic Brain Injury Committee[5] criteria to define mTBI and four studies did not report a specific criteria used to determine TBI severity.

Two studies[32]reported that people with a history of previous TBIs were excluded and two studies reported that 22.0%[35] and 30.4%[31] of participants had a history of previous TBIs.

Intervention Characteristics of Included Studies

Details of interventions reported by included studies are provided in Table 2.

Table 2. Summary of Intervention Characteristics

Study	Intervention Content	Intervention Duration	Intervention Mode	Intervention Delivered By	Control	Attrition Rates %	
						Intervention	Control
Andersson 2007[30]	*Psychoeducation and further assessment* The intervention involved oral information, counselling, encouragement and assessment of need; patients were referred to services according to need where bespoke interventions were delivered.	Unclear	Individual, outpatient for "first weeks" followed by telephone contact	Rehabilitation Specialist	Treatment as usual	15.9	16.8
Ghaffar 2006[31]	*Psychoeducation and further assessment* Standardised psychoeducation regarding postconcussion and mTBI symptoms. Further assessment of clinical need also provided. Where needed, pain, headache dizziness, emotional and sleep symptoms were addressed using psychopharmacology, psychotherapy, physiotherapy and occupational therapy.	Unclear	Individual outpatient (although participants encouraged to attend with spouse)	Occupational Therapist	Treatment as usual	11.3	10.6
Matuseviciene 2013[32]	*Psychoeducation and further assessment* Patients in the treatment group received a screening for anxiety and depression; interview and examination of symptoms including reassurance regarding favourable outcome and recommendations for gradual return to activities. Pharmacological treatments and referrals were made according to identified need.	One visit (duration unclear)	Individual	Physician; specialist in rehabilitation medicine	Treatment as usual	18.8	16.3
Mittenberg 1996[33]	*Psychoeducation and CBT* Patients in the treatment group received a 10 page printed manual, "Recovering From Head Injury: A Guide for Patients" (Mittenberg, Zielinski & Fichera, 1993) and met with therapist to review the nature and incidence of expected symptoms. The CBT model and techniques for reducing symptoms were employed. The intervention was intended to support the reattribution of symptoms to selective attention, normal transient responses to stress, anxiety and low mood.	One hour	Individual	Therapist (professional background unspecified)	Treatment as usual	Not reported	Not reported

Scheenen 2017[34]	*Psychoeducation and CBT* Patients in the treatment group received standardised psychoeducation on mTBI. CBT strategies included cognitive restructuring of negative thoughts and planning/structuring daily activities to manage fatigue. Patients also received a copy of "Recovery after mild TBI: a guide for patients and their families" (Mittenberg, Zielinski & Fichera, 1993).	Five one-hour sessions within 4-10 weeks post-injury	Group (2-4 participants)	CBT-Certified Psychologists	*Individual telephone counselling* Five telephone calls 4-8 weeks after discharge providing reassurance about course of symptoms delivered by a Psychologist and Physician	11.4	4.3
Silverberg 2013[35]	*CBT* Based on work of Mittenberg but also incorporated strategies developed for managing health anxiety and medically unexplained symptoms. Primary goal to alter maladaptive beliefs and coping behaviours associated with chronic PCS, addressing this within the CBT framework. The paper reported that strategies included collaborative empiricism, guided discovery and Socratic questioning.	Six weekly 50-minute sessions	Individual	Doctoral-Level Psychologists with specialist training in neuropsychology	Treatment as usual*	15.4	13.3
Suffoletto 2013[36]	*Psychoeducation and Reassurance* All participants received a daily text asking them to record their level of headache, concentration difficulty and irritability or anxiety symptoms in the previous 24 hours. In the intervention condition, those who reported severe symptoms received another automated text detailing symptom specific education, reassurance and management guidance. This intervention was named TXT to Improve Post-Concussion Symptoms (TIPS)	14 days	Text messaging	Telephone text Material developed by ED MDT: emergency physicians (2), physical medicine and rehabilitation specialists (2)	Treatment as usual	22.0	12.0
Wade 1997[37]	*Psychoeducation and Further Assessment* Participants in the intervention group were given written information regarding management of possible symptoms following mTBI. Participants were also contacted by a clinician for further assessment of clinical need. Participants were referred to other services where clinical need was identified.	One session	Individual Telephone or Face to Face (depending on availability of participant)	Occupational Therapist and Clinical Psychologist	Treatment as usual	56.3	60.8
Wade 1998[38]	*Psychoeducation and Further Assessment* Participants in the intervention group were given written information regarding management of possible symptoms following mTBI. Participants were also contacted by a clinician for further assessment of clinical need. Participants were referred to other services where clinical need was identified.	One session	Individual Telephone or Face to Face (depending on availability of participant)	Occupational Therapist and Clinical Psychologist	Treatment as usual	28.3	33.8

*Treatment as usual involved written information and routine 3-hour session with concussion clinic were as standard. In this session psychoeducation was provided, strategies for symptom management were suggested and gradual return to activities was advised.

The most common psychological intervention examined in the present review was a combined psychoeducation and further assessment intervention, being reported by five studies[30-32,37,38]. One study[36] examined a psychoeducation and reassurance intervention. Three studies[33-35] explored a CBT intervention. Most studies compared intervention conditions to treatment as usual control conditions, however one study[34] examined an active control group.

The duration of the interventions ranged from a single session[32,33,37,38] to six weekly sessions[35]. The majority of interventions were delivered on an individual basis with only one study[34] reporting a group psychological intervention, however this was compared to an individual telephone counselling control condition.

Effects of Interventions

Where post-intervention summary data were available, Hedge's *g* was calculated to indicate the effect size. If insufficient summary data was reported for Hedges *g* to be calculated, Cohen's *d* was reported. These results are reported for the primary outcome in Table 3.

Table 3. Post-Concussion Outcomes Reported by Included Studies

Intervention	Control	Study	Follow-up Period	Measure	Effect Size (Hedges g)
Psychoeducation and Further Assessment	Treatment as Usual	Andersson 2007[30]	One year	NSPCSQ	-0.151
		Ghaffar 2006[31]	Six months	RPQ	0.062
		Matuseviciene 2013[32]	Three months	RPQ	Insufficient data reported
		Wade 1997[37]	Six months	RPQ	0.327
		Wade 1998[38]	Six months	RPQ	-0.086
Reassurance		Suffoletto 2013[36]	14 days	RPQ	0.205*1
CBT		Mittenberg 1996[33]	Six months	SC	Severity: 0.574; Frequency: 0.545
		Silverberg 2013[35]	Three months	RPQ	0.723
	Telephone Counselling	Scheenen 2017[34]	Three months	HISC	-0.604*2
		Scheenen 2017[34]	Six months	HISC	Insufficient data reported
		Scheenen 2017[34]	One year	HISC	-0.648*2

NSPCSQ= The New Swedish Post Concussion Symptoms Questionnaire; RPQ=Rivermead Post-Concussion Questionnaire; SC=Symptom Checklist; HISC=Head Injury Symptom Checklist

**1 Mean and SD estimated from median and interquartile ranges used to calculate Hedges g*

**2 Cohen's d reported as insufficient data provided to calculate Hedges g*

Follow-up periods ranged from 14 days[36] to one year[30,34]. Only one study[34] reported outcomes at multiple follow-up periods.

Post-Concussion Symptoms

Of the eight studies comparing a psychological intervention with treatment as usual, two studies[33,38] reported a statistically significant result in favour of the intervention group; one study[33] found that participants in the intervention condition reported significantly less severe (p=0.02) and less frequent (p=0.02) PCS compared with participants in the control group and one study[38] found that participants in the intervention group reported significantly lower scores on the RPQ (p=0.02).

Effect sizes were calculated using post-intervention data only as baseline summary data was reported in only a minority of studies. A significant baseline imbalance was only reported in one study[32]. This imbalance was no longer significant at follow up.

Overall, calculated effect sizes ranged from g=-0.151[30] (in favour of the control group) to g=0.723[35] (in favour of the intervention group). No effect size could be calculated for PCS outcomes in two studies due to insufficient summary data being available[32,34].

Of the five studies[30-32,37,38]comparing a psychoeducation and further assessment intervention with a treatment as usual condition, the effect sizes ranged from g=-0.151[30] (in favour of the control group) to g=0.327[38] (in favour of the intervention).

Of the studies reporting medium to large effect sizes, two studies[33,35] reported medium to large effect sizes (Hedges *g* ranging from 0.545[33]to 0.723[35]) in favour of a CBT intervention compared with a treatment as usual control condition. Whilst one study[33] reported that this effect was statistically significant, one study[35] was not adequately powered to detect if the effect size reported was significant. One study[34] reported a medium to large effect size

(Cohen's *d* ranging from 0.604 to 0.648, depending on follow-up time reported) in favour of the one to one telephone counselling control condition compared with a combined psychoeducation and CBT group-based intervention.

Anxiety

Two studies[32,36] reported outcomes of anxiety symptoms. One study[32] reported no significant group difference in mean anxiety scores on the Hospital Anxiety and Depression Scale (HADS) at three-months ($g<0.001$, metric not reported, p value not reported). One study[36] reported no significant difference in the number of people reporting significant symptoms of anxiety, between the psychological intervention (42.9%) and treatment as usual (45.5%) groups, as measured by the Patient Health Questionnaire-4 (PHQ-4;), at 14-day follow-up ($\chi^2=0.023$, $p=0.878$). However, study authors did not specify the cut off used to determine significant symptoms.

Depression

Three studies[31,32,36] reported symptoms of depression outcomes. One study[31] reported no significant difference in symptoms of depression as measured by the General Health Questionnaire, between the psychological intervention and control group at six months ($g=0.026$, $p=0.90$). One study[32] also reported no significant difference between the psychological intervention and treatment as usual control in depression symptoms as measured by the HADS, at three months ($g=0.183$, metric not reported, p value not reported). One study[36] reported no significant difference in the incidence of significant symptoms of depression, between the psychological intervention (42.9%) and the treatment as usual (13.6%) groups as measured by the PHQ-4 at 14-day follow-up ($\chi^2=2.534$, $p=0.111$).

Quality of Life

Only one study[30] reported outcomes of quality of life. No significant difference (p valued not reported) was reported between the intervention and control condition on any of the subdomains of the Short Form 36 (SF-36). Effect sizes for these differences could not be calculated due to insufficient summary data being reported. Total SF-36 scores were not reported.

Cognitive Symptoms

None of the included studies reported outcomes of self-reported cognitive symptoms.

Attrition Rates

Attrition rates in the intervention group ranged from 11.3%[36] to 56.4%[37] and attrition rates in the control group ranged from 4.3%[34] to 60.8%[37]. There was no statistical difference between attrition rates for intervention and control groups reported in the included studies.

Risk of Bias

A summary of risk of bias ratings is provided below. Further details regarding risk of bias judgements are provided in Appendix S.

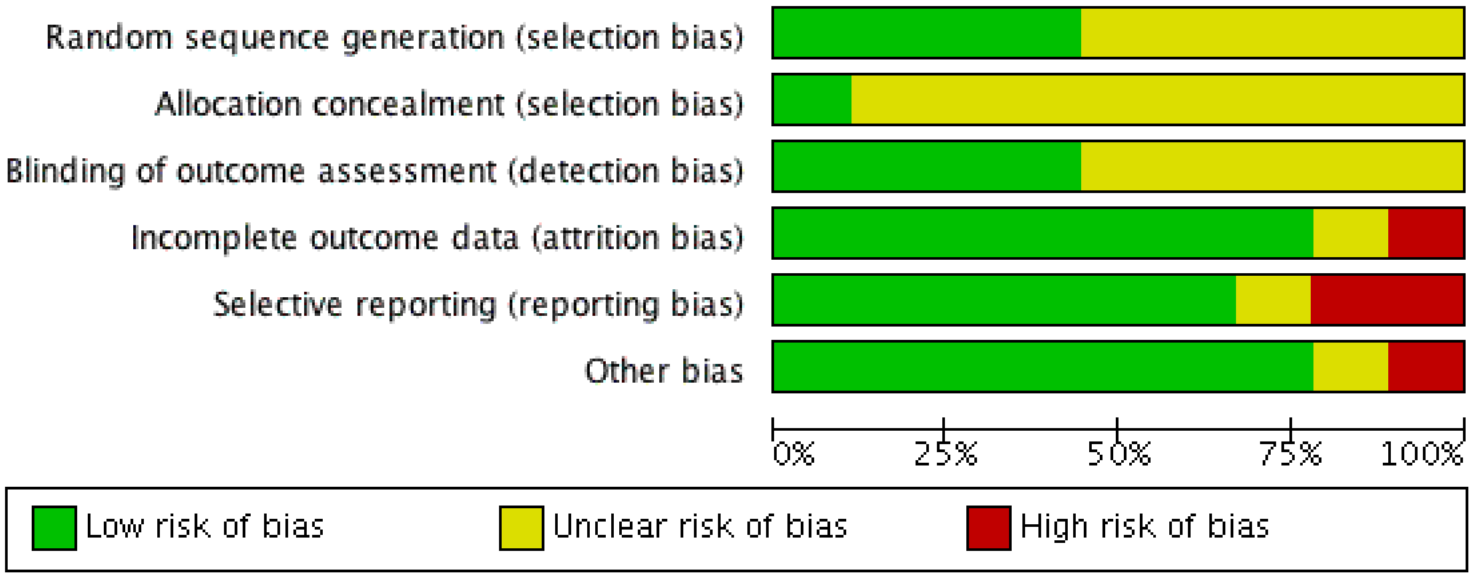

FIG 2. Risk of Bias Assessment Graph of Included Studies (created in Review Manager 5.2)

Five studies[30,35-38]were rated as having low risk of sequence generation bias and four studies[31-34] were rated as unclear. One study[35] was rated as having low risk of allocation concealment bias and eight studies[30-34,36-38] were rated as unclear. Five studies[30,33,34,37,38] were rated as having low risk of blinding of outcome assessment bias and four studies[31,32,35,36] were rated as unclear. Six studies were rated as low risk of incomplete outcome data bias, two were rated as high risk of incomplete outcome data bias and one study was rated as unclear. Protocols were available for two studies[35,36]. Selection bias was not identified in any of the included studies. Additional potential sources of bias were also noted in one study[33].

Quality Appraisal

The overall GRADE quality assessment for the evidence of psychological interventions for the prevention of persistent PCS was rated as very low quality. This was largely due to the limitations of individual study methodologies and the heterogeneity across studies, preventing pooled estimates to be calculated.

The quality of evidence for secondary outcomes of anxiety, depression, quality of life and study attrition was further limited as few included studies reported these outcomes.

Discussion

The present review aimed to examine which psychological approaches for preventing PPCS have been explored and to evaluate the implications, quality and overall completeness of this evidence.

The most common intervention included in the present review was a combination of psychoeducation and further assessment, which then determined subsequent referrals to services. The evidence for this approach did not indicate strong support with the majority of studies reporting small and non-significant findings. Four studies reported findings from standardised psychological interventions; three examined a combined psychoeducation and

CBT intervention and one study reported findings from a psychoeducation and reassurance intervention delivered by text.

Evidence for a CBT approach appeared more positive with two of the three studies[33,35] reporting large effect sizes in favour of the individual intervention condition compared with a treatment as usual control. One study[34] compared an individualised one-to-one psychological treatment delivered via telephone with a standardised group-based psychological treatment and reported medium to large effect size in favour of the individualised one-to-one psychological intervention.

The majority of studies included in the present review consecutively recruited people presenting with head injury to hospital services. Considering that a large proportion of people who sustained a MTBI are expected to make a full recovery with no or little intervention[7], it is likely that many of the people recruited in these studies would make a full recovery irrespective of whether they received the intervention or treatment as usual. This means that the expected base rate of symptomatic participants at follow-up would have been very low regardless of treatment, making it more difficult to identify an effect. This was noted by Wade et al.[38] who found a significant treatment effect for a psychoeducation and further assessment intervention in a second RCT despite using the same methodology and procedure as in the first RCT[37], which reported no significant treatment effect. The authors noted that the sample of participants in the second RCT[38] included a considerably higher proportion of people who were symptomatic compared with the first RCT[37], which resulted in a higher base rate and is why the results of the second RCT[38] were statistically significant.

Three studies[30,34,35] screened only participants who were considered to be at risk of experiencing persistent symptoms. Of these, two studies[30,35] compared a psychological intervention with a control group for people considered to be at risk of developing persistent PCS. One study[35] reported a large effect size in support of an individual CBT intervention

compared with treatment as usual. However, one study[30] screened participants after they had been randomised into the intervention group and only those considered at risk were offered the intervention, yet all participants in the intervention group were entered into the analysis irrespective of whether they had received an intervention. This study reported a small effect size in favour of the control group, although this was not significant. Finally, one study[34] reported a significant medium to large effect size in favour of individual psychological intervention delivered via telephone compared with group-based psychological intervention.

Whilst many studies report that groups can be an effective mode of intervention delivery[39], some research has highlighted that group interventions are less effective and may produce adverse effects in some populations, including adolescence with conduct disorders[40] and people in inpatient mental health settings[41]. Therefore, further exploration of different treatment modes is warranted with specific attention to potential contraindications of group therapy.

Considering these findings, the present review indicates that there is some limited evidence to suggest an early individual group CBT intervention may be effective in preventing persistent symptoms in people who have sustained a MTBI. However, this evidence derives from only two studies; both of which were underpowered to detect whether the effect size reported was significant.

Overall, the psychological interventions reported in the present review were well tolerated; no studies reporting significantly higher attrition rates for the intervention condition compared with those reported for control conditions. Similarly, no study reported that participants experienced a significant increase in PCS at follow-up, therefore there is no evidence to suggest that such interventions may be harmful.

There are a number of methodological differences between the present review and a previous review conducted by Mittenberg[22]. Only two of the nine outcome studies included in the Mittenberg[22] review were included in the present review. The reason for this is that the present review included only RCTs, whereas Mittenberg[22] included uncontrolled and non-randomised studies. Additionally, the present review included only studies that reported standardised outcome measures of PCS, whereas Mittenberg[22] reported studies using unstandardised measures of PCS. The inclusion of only standaridised measures of PCS in the present review facilitates greater confidence that the assessment of symptoms conducted in the studies was valid and reliable.

There are a number of limitations to the present review. Despite employing stringent eligibility criteria, the present review highlighted considerable clinical and methodological heterogeneity across included studies. There was variation in interventions both across and within included studies; in studies adopting a further assessment element to the psychological interventions, participants were often referred to other services and therefore received additional support according to identified clinical need.

There was also variation in what constituted the control groups across included studies. Although most included studies reported a treatment as usual control condition, this may have varied according to local service provision.

Due to considerable clinical and methodological heterogeneity, meta-analysis was not appropriate. Therefore, calculating pooled estimates of effectiveness of psychological interventions was not possible and findings were synthesised narratively.

The present review examined only early interventions for the prevention of PPCS in people who have sustained a MTBI. The present review does not provide any evidence for the

efficacy of psychological intervention for people with mTBI who are experiencing PPCS as this is the focus of a separate review[6].

It cannot be guaranteed that all relevant literature was identified, particularly as definitions and terminology around PCS is widely variable and debated throughout literature and practice. However, it is believed that the search strategies employed in the present review are comprehensive, minimising the risk of unintentionally omitting any relevant literature.

Finally, whilst most studies included only participants considered to have mild TBI, a minority of studies included a small proportion of participants who had moderate to severe TBI. Furthermore, a number of studies did not provide details regarding what diagnostic criteria were used to determine severity of brain injury. Equally, few studies reported on previous brain injury, which has been indicated as contributing to outcome following TBI. Therefore, whether the severity of injuries was consistent across studies is unclear.

In terms of implications for further research, the current review highlights inconsistent findings on a background of methodological limitations. Whilst it is evident that further high quality research is required in order to evaluate the effectiveness of psychological intervention for the prevention of PPCS, it is important that further research addresses the key questions arising from the present review.

The evidence for psychological interventions for preventing persistent PCS remains in its infancy. The majority of included studies adopted a non-standardised intervention approach with referrals being dictated by clinical need. From this, it is difficult to identify the effective elements of such interventions with participants within these studies receiving different types and varying levels of support. Research adopting standardised intervention approaches will enable the efficacy of psychological interventions in this area to be more accurately considered. The studies which adopted a standardised intervention were limited to

psychoeducation, reassurance and CBT. Developments in application of other psychotherapeutic approaches, such as mindfulness based cognitive therapy[42] (MBCT) would also be candidates for future research exploring preventative psychological interventions for PPCS.

Additionally, the included studies recruiting specifically people considered to be at risk of developing PPCS produced the largest effects. This would also be a more cost-effective process as many people who have sustained a MTBI would be expected to make a good recovery without additional support[7]. This also has implications for further research examining the factors that predict the development of PPCS in people presenting with mTBI. At present, there does not appear to be any multivariate prognostic models that sufficiently predict those at risk of PPCS[35]. Further research examining factors that predict PPCS would promote more accurate identification of those most at risk.

In terms of implications for practice, the present review suggests that the early identification of those considered to be at risk of developing PPCS may be important for effectively targeting provision of early psychological intervention provision. The evidence for the efficacy of early psychological interventions for preventing PPCS is mixed. The most promising evidence comes from studies reporting CBT interventions, particularly in those recruiting people considered at risk of PPCS and where interventions were delivered by Clinical Psychologists with further specialist training in neuropsychology. In contrast, those reporting outcomes for combined psychoeducation and further assessment interventions were much less convincing. However, these conclusions remain tentative due to the considerable heterogeneity and low quality of evidence across a limited number of studies.

Conclusion

In conclusion, the available research evidence indicates that PPCS represents a significant area of clinical need. To date, there is only limited available evidence indicating that early intervention with high risk individuals may be effective for reducing PPCS. It is hoped that further research exploring positive predictors of PPCS and the effectiveness of early interventions to prevent PPCS will inform the evidence-based development of services to support and promote a quick and full recovery.

Funding

The present review was funded as part of the Doctorate in Clinical Psychology programme at the University of Liverpool.

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Chapter 3: Investigating the Impact of Self-Criticism and Self-Reassurance on the Experience of Distress People with Traumatic Brain Injuries

Target Journals:

Journal of Head Trauma Rehabilitation (2.7)

ABSTRACT

Objective: To examine whether psychological processes involved in self-appraisal and responses to aversive internal experiences are significant factors in understanding the levels of distress experienced by people following Traumatic Brain Injury (TBI). **Participants:** One hundred and fifteen people with TBI completed a set of questionnaires. **Design:** A cross-sectional/observational design employing a multiple hierarchical regression analysis. **Main Measures:** Emotional distress as measured by Depression Anxiety and Stress Scale – 21 item (DASS-21); self-criticism and self-reassurance as measured by Forms of Self-Criticism/Attacking and Self-Reassurance Scale (FSCRS); psychological inflexibility as measured by Flexibility of Responses to Self-Critical Thoughts (FoReST). **Result:** Self-criticism, self-reassurance and psychological inflexibility explained an additional 30% of variance in emotional distress beyond demographic, clinical and injury-related factors, with only self-criticism making a significant independent contribution. Exploratory moderation analysis revealed that there was no significant effect on emotional distress when considering the interaction between self-criticism with self-reassurance and psychological inflexibility. **Conclusion:** While emotional distress is common following TBI, there remains no demographic, clinical or injury-related factors that have demonstrated consistent associations with the level of emotional distress experienced. The present study demonstrates that psychological factors, relating to personal evaluations, explains considerable variance in emotional distress beyond demographic and injury-related factors. These processes may help

identify those at risk of poorer emotional outcomes following TBI, and targeting these processes via psychological interventions may improve emotional wellbeing in these people.

Key words: brain injury, emotional distress, self-criticism, self-reassurance, psychological inflexibility

INTRODUCTION

The consequences of traumatic brain injury (TBI) are multifaceted, with survivors sometimes experiencing a cascade of lasting difficulties including cognitive, communication, physical, chronic pain, personality, mood and behavioural difficulties[1]. There are also many indirect consequences of TBI such as unemployment[2] and greater incidence of relationship instability[3]. People who have sustained a TBI are at an elevated risk of experiencing psychological comorbidities with the prevalence of anxiety and depression significantly greater in people who have sustained a TBI compared with the general population[4-6].

Factors Associated with Psychological Distress in People with TBI

Exploration of factors which may be associated with depressive symptoms in people with TBI has yielded mixed results. Some studies have reported associations between demographic factors including age, gender and education with poorer psychological outcomes[7-9], however other studies have reported no significant association in these factors[10].

Previous studies have shown that pre-injury psychological difficulties, such as anxiety and depression, were significantly associated with post-injury psychological outcomes[7,9]. An early theoretical model proposed that cognitive difficulties have been implicated as impacting on an individual's ability to adjust psychologically following TBI[11]. However, whilst some studies have reported a significant association between cognitive functioning and psychological outcomes[12], others have not[13]. Other clinical factors have also been highlighted, such as pain and fatigue, as contributing to emotional distress, although evidence for these associations has been debated[14,15]. Finally, there has been no consistent evidence suggesting a

significant association between injury severity and psychological outcomes, with the majority of studies reporting no significant relationship[10,16,17]. To date, there has been little consistency across studies in regards to the relationship between emotional distress and demographic and injury related factors. Therefore it is likely that other processes are contributing to emotional distress in people with TBI.

People with TBI face a plethora of symptoms that often prevent, or complicate, the return to pre-injury life. Activities that individuals completed with little effort prior to their injury may be experienced as more challenging post injury due to acquired physical or cognitive difficulties. Qualitative research has highlighted that people report struggling with changes to self-identity and the loss of their pre-morbid self-identity following TBI[18,19]. Additionally, the experience of shame and the sense of being a burden on society has also been highlighted through qualitative research[20, 21]. Therefore, qualitative research has highlighted general themes regarding the content of aversive internal experiences often reported by people following traumatic brain injury.

Psychological Therapies for People with TBI

The most commonly reported psychological interventions for such experiences in people with TBI have largely been based on traditional Cognitive Behavioural Therapy[22,23] (CBT) approaches. This approach focuses on the content of negative thoughts and encourages individuals to develop evidence-based alternatives, to challenge these thoughts. Research has consistently demonstrated strong empirical support for CBT in non-TBI populations[24]. In people with TBI however, the evidence base is more limited. A recent review[25] identified three randomised controlled trials (RCTs) that had assessed the efficacy of psychological interventions for reducing symptoms of depression in people with TBI. Two studies assessed the efficacy of CBT[4,26] and one study assessed the efficacy of Mindfulness-Based Cognitive Therapy[27]. The two studies that found favourable results in favour of psychological

interventions however, reported small effect sizes[4,27], with one study reporting results in favour of the waiting list control[26].

More recent advances have highlighted limitations of CBT, particularly with researchers arguing that changing the content of thoughts is not always possible or necessary for clinical change[28]. In recognition of this, a range of novel interventions have been developed that are sometimes referred to as 'third wave' psychological interventions. Unlike CBT, these approaches seek not to change or eliminate negative thoughts, but to change the relationship individuals have with internal experiences to influence clinical change[28-31]. Compassion Focused Therapy[29,30,32-34](CFT) and Acceptance and Commitment Therapy[26,29,33] (ACT) are examples of third-wave CBT approaches and have been highlighted as potentially beneficial for people with TBI[35,36].

Compassion Focused Therapy and TBI

CFT literature highlights the role of self-criticism and self-compassion or self-reassurance in response to perceived failures or criticism. Central to a CFT approach is the development of self-compassion or self-reassurance, which both refer to a kind and soothing way of responding to perceived shortcomings or criticism[37]. Theoretically, a CFT model would predict that someone with low self-reassurance and high levels of self-criticism would experience higher levels of emotional distress. This is supported by empirical evidence from studies reporting significant associations between self-criticism, self-reassurance and emotional distress in non-clinical populations[38] and clinical populations including people diagnosed with eating disorders and women diagnosed with cancer[39]. The relationship between self-criticism, self-reassurance and emotional distress has not been explored in people with TBI.

Evidence for CFT for people with TBI from intervention studies is limited. Ashworth et al.[24] adopted a mixed methods approach in which 12 participants completed standardised

measures and qualitative interviews prior to and following an 18-week neurorehabilitation programme. Within this programme, there was a six-week mood group that integrated CFT. Findings revealed that symptoms of anxiety and depression reduced significantly as post-intervention and three-month follow-up. It is unclear however, whether this was due specifically to the CFT part of the total neurorehabilitation programme.

Acceptance and Commitment Therapy and TBI

ACT[28,31,40] hypothesises that difficulties often emerge when people become experientially avoidant of aversive thoughts and emotions. In ACT, individuals are encouraged to broaden restrictive efforts aimed at controlling unwanted internal experiences to embrace a more expansive range of behavioural repertoires, that are consistent with their values. This process is often referred to as becoming more psychologically flexible[31]. According to an ACT approach, people with greater psychological inflexibility will experience higher levels of emotional distress, which has been demonstrated in non-clinical samples[41,42] and clinical samples such as people with chronic pain[43].

Within a TBI population, one study[44] reported data from 68 participants with acquired brain injury who completed a series of questionnaires. The results of this study indicated that participants' scores on a standardised measure of acceptance was positively correlated with scores on a measure of health-related quality of life.

Evidence for the efficacy of ACT interventions for people with TBI is also extremely limited. One published case series[45] reports pre- and post-intervention scores on measures of depression and anxiety for two male participants who had received seven sessions of ACT. One participant showed significant and reliable change on both measures of anxiety and depression whereas the other participant indicated no change.

Aims of Present Study

Process-focused approaches may be particularly advantageous for people with TBI as challenging the content of thoughts sometimes may not be appropriate. For example, "I cannot return to my old job" may be a valid and rational thought for someone who has sustained significant physical or cognitive difficulties and has been in an active or cognitively demanding role.

Gracey, Evans and Malley (2009)[46] highlighted the importance of developing psychotherapeutic interventions for people with TBI based on empirically supported psychological models. As discussed, there remains only limited empirical support for the theoretical models of both CFT and ACT. Therefore, the present study aimed to explore the relationships between emotional distress and psychological constructs central to these theoretical models. Understanding the factors that contribute to emotional distress in people with TBI may provide important information to guide therapeutic targets and identify those at risk so support can be offered early in order to improve psychological outcomes.

Hypotheses

1. Higher levels of emotional distress will be associated with:
    a. Higher levels of self-criticism
    b. Lower levels of self-reassurance
    c. Higher levels of psychological inflexibility
2. Self-criticism, self-reassurance and psychological inflexibility will explain additional variance in levels of emotional distress beyond demographic and injury-related factors.
3. Self-reassurance and psychological inflexibility will moderate the association between self-criticism and emotional distress.

METHOD

Design

This study adopted a cross-sectional, observational design. The study assessments were available both online and were also offered as paper-based for participants recruited locally.

Participants

The inclusion criteria were as follows: (i) aged between 18-69 years (ii) history of TBI or concussion; (iii) able to read, understand and complete a questionnaire written in English.

Exclusion criteria are: (i) participants who have sustained a non-traumatic brain injury with an underlying organic cause (stroke, infection, tumours); (ii) unable to read and understand questionnaires written in English language.

An a priori analysis was calculated using G*power[47], using a multiple regression analysis with 15 predictors, a power of 80% and a conservative effect size of 0.25. This led to a sample of 89. The effect size of 0.25 was chosen as the minimum effect size which would be clinically relevant and therefore all effect sizes stronger than this would be adequately powered.

Measures

Demographic Questionnaire

A *Demographic and Clinical Questionnaire* was developed to collate information regarding: age, gender, time since injury, age at injury, nature of injury, severity of injury, epilepsy, previous or on-going litigation and who the respondent believed to be responsible for the injury. Participants were asked to report the duration of loss of consciousness on which judgements were made regarding the severity of injury in accordance with the US Department of Defense and Department of Veteran Affairs[48] diagnostic criteria.

Emotional Distress

The *Depression, Anxiety and Stress Scale*[49] (*DASS-21*) is a 21-item self-report measure used to measure the severity of depression, anxiety and stress symptoms. This measure displays strong internal consistency (Cronbach's α of 0.96 and 0.97 for depression, 0.84 and 0.92 for anxiety, and 0.90 and 0.95 for stress[49,50]). Normative data has been published for a nonclinical UK adult sample[51]; the reported mean score for total was 9.43 (9.66), for depression was 2.83 (3.87), for anxiety was 1.88 (2.95) and for stress was 4.73 (4.20).

Quality of Life

Quality of Life after Brain Injury[52] (*QOLIBRI*) consists of 37 items from six subscales: cognition, self, daily life and autonomy, social relationships, emotions and physical problems, which have strong internal consistency (Cronbach's α of 0.75)[43,52].

Injury-Related Factors

Everyday Memory Questionnaire- Revised[53] (*EMQ-R*)*:* The Everyday Memory Questionnaire (EMQ) was designed to assess individuals' memory difficulties in everyday life for survivors of TBI. The original questionnaire included 28 items but this was reduced to 13 items in the revised version. The EMQ-R has been shown to have strong internal consistency[54] (Cronbach's α of 0.91).

Brief Pain Inventory – short form[53] (*BPI-SF*) is a 9 item self-report questionnaire developed to assess the severity of pain and has been shown to have greater internal consistency for patients with injury/trauma related pain[54] (Cronbach's α of 0.85 and 0.88 for severity and interference of pain).

Fatigue Severity Scale[55] (*FSS*) is a self-report, seven point likert questionnaire assessing fatigue severity, with strong internal consistency (Cronbach's α = 0.90) within a TBI population[56].

Psychological Inflexibility

The Flexibility of Responses to Self-Critical Thoughts Scale[57] (FoReST) is a 12 item self-report questionnaire measuring individuals' psychological flexibility around self-criticism. This measure has strong internal consistency[57] (0.80 to 0.92). Higher scores indicate lower psychological flexibility and therefore greater psychological inflexibility. Therefore scores on the FoReST will be referred to as psychological inflexibility.

Self-Criticism/Self-Reassurance

Forms of Self-Criticism/Attacking and Self-Reassurance Scale[34] (*FSCRS*) is a 22 item self-report questionnaire, which measures both self-criticism and self-reassurance/self-compassion and has been shown to have strong internal consistency[58] (0.87 to 0.94). A composite score for 'self-criticism' (FSCRS SC) can be obtained by combining scores on the 'Inadequate self' and 'Hated Self' subscales[59].

Procedure

An online questionnaire was developed using the Qualtrics platform. This is a secure site that is routinely used for collecting research data from questionnaires. Paper copies of the questionnaires were also created and formatted consistently.

Participants were recruited from three sources: (1) the researcher attended neurotrauma clinics at The Walton Centre NHS Foundation Trust and patients attending clinics were provided with information and the opportunity to take part; (2) local and national charity organisations within Headway UK were contacted and information about the present study was circulated to members. Additionally, the researcher attended local headway groups to provide information to potentially interested participants; (3) private providers of neurorehabilitation services (4) advertisements were placed in social media support groups, providing a link to the online questionnaire.

Participants recruited locally were provided the opportunity to complete paper versions of the questionnaires or to complete the online questionnaires. Participants who were not local were provided only the opportunity to complete the questionnaires online.

Ethics

Research Ethics Committee (REC) approval was obtained prior to commencement of recruitment from non-NHS sites (Appendix I; reference number: 17/WS/0232). Further Health Research Authority (HRA) approval (Appendix L) and Documentation of Capacity and Capability (Appendix K) from The Walton Centre Research and Development Department was obtained prior to commencement of NHS recruitment. This was in accordance with guidance from the REC.

All participants were provided with a Participant Information Sheet (PIS: Appendix C) which outlined the study aims, expected benefits and planned strategy for dissemination of results. Participants also completed a signed consent form (either electronically or paper form). All identifiable data was removed from the data when entered into the database to ensure anonymity. Participants were informed that participation was voluntary and were informed that they possessed the right to withdraw from the study at any time.

Statistical Analysis

Statistical analysis was completed using the Statistical Package for Social Sciences (SPSS) version 22. Pair-wise deletion was carried out for one participant who did not provide a response for duration of LoC. An alpha level of <0.05 was used to evaluate significance.

To test the first hypothesis, a preliminary correlation analysis was carried out to explore the relationship between emotional distress, self-criticism, self-reassurance and psychological inflexibility.

A hierarchical linear regression was completed to examine the second hypothesis that self-criticism, self-reassurance and psychological inflexibility would explain additional

variance in distress (as measured by the DASS-21), beyond demographic and injury-related factors. Predictor variables were entered in the following order: Step 1. age, gender, education, time since injury and history of pre-morbid psychological difficulties; Step 2. severity of injury, cognitive complaints (EMQ), pain (BPI), fatigue (FSS) and litigation; Step 3. self-criticism (FSCRS), self-reassurance (FSCRS) and psychological inflexibility (FoReST).

Severity of injury was dummy coded as there were more than two categories reported: moderate (vs. mild and severe) and severe (vs. mild and moderate). For gender, litigation and psychiatric history, only one participant did not fall within the two main groups, therefore these variables were condensed: male or female, litigation or no litigation, psychiatric history of no psychiatric history. Education was also condensed into dichotomous variables: higher education (A-Levels, Bachelor's, Master's and PhD/Doctorates) and no higher education (no qualifications, GCSE/O-Levels, vocational qualifications). Where there was missing data, pairwise deletion was carried out.

To test the third hypothesis, a moderation analysis was completed in Step 4 of the multiple regression. Self-criticism (FSCRS), self-reassurance (FSCRS) and psychological inflexibility (FoReST) were mean centred and multiplied to produce two additional variables (FSCRS SC x FSCRS RS and FSCRS SC x FoReST PF).

RESULTS

Descriptive Statistics

A total of 118 participants completed the questionnaire; 115 participants completed the online version and three participants completed paper copies. The age of participants ranged from 18 to 69 years old. Time since injury ranged from 4 months to 67 years. Demographic, injury related and clinical characteristics are shown in Table 1 and Table 2.

Mean depression, anxiety and total DASS-21 (emotional distress) scores were over one standard deviation higher compared with published normative data[49]. Furthermore, 54% of participants scored within the *severe* range of the depression subscale, 20% of participants scored within the *moderate* range of the depression subscale and 26% scored within the *normal or mild range*. For the anxiety subscale, 70% of participants scored within the *severe* range, 13% scored in the *moderate* range and 17% scored in the *mild or normal range*.

Table 1. Demographic and Injury Characteristics of Participants (n=118)

Demographic Characteristics		
Age (years; mean, SD)		45.42 (11.75)
Gender (%)	Male	39.9
	Female	59.3
	Nonbinary	.8
Education (%)	Higher education	57.6
	No higher education	42.4
Time Since Injury (years; median, IQR)		5.41 (2.41-17.24)
Psychiatric History (%)	Yes	26.3
	No	72.9
	Prefer not to say	0.8
Injury Characteristics		
Duration of loss of consciousness (%)	0-30 minutes	47.5
	30minutes – 24 hours	18.6
	Over 24 hours	33.1
	Unknown	0.8
Nature of Injury (%)	RTA	39.0
	Assault	10.2
	Military incident	0.8
	Sports injury	5.1
	Fall	24.6
	Struck by/against object	5.1
	Other	15.3
Litigation (%)	Completed	16.9
	Ongoing	15.3
	No	65.3
	Prefer not to say	2.5
Others injured (%)	Yes	15.3

	No	83.9
	Prefer not to say	0.8
Fatalities (%)	Yes	4.2
	No	94.9
	Prefer not to say	0.8
Epilepsy (%)	Yes	8.5
	No	90.7
	Prefer not to say	0.8

Table 2. Clinical Characteristics of Participants (n=118)

Measures		**Mean (SD)**
DASS-21	Total	25.03 (12.65)
	Depression	6.14 (4.08)
	Anxiety	9.03 (5.39)
	Stress	9.85 (5.14)
QOLIBRI		102.62 (24.93)
FSS		47.52 (13.89)
BPI Severity		12.20 (10.04)
EMQ		32.88 (14.36)
FoReST PI		39.83 (14.02)
FSCRS	Self-Criticism	22.12 (12.57)
	Self-Reassurance	15.36 (7.12)

DASS-21=Depression, Anxiety and Stress Scale – 21 item; QOLIBRI=Quality of Life after Brain Injury; FSS=Fatigue Severity Scale; BPI=Brief Pain Inventory; EMQ=Everyday Memory Questionnaire; FoReST PI=Flexibility of Responses to Self-Critical Thoughts- Psychological Inflexibility; FSCRS=Forms of Self Criticising/Attacking and Self-Reassurance Scale

Bivariate Analysis

Correlation analysis between the outcome and exploratory variables are displayed in Table 3. As can be seen, there were significant correlations between all variables, with all exploratory variables showing a moderate to strong association to the emotional distress outcome. A weak negative association was observed between psychological inflexibility and self-reassurance.

Table 3. Pearson's Correlations Between Study Variables

Variable	**FSCRS SC**	**FSCRS RS**	**FoReST PI**
DASS-21	0.64***	-0.49***	0.55***
FSCRS SC	-	-0.58***	0.62***

FSCRS RS	-	-0.35***
FoReST PI		-

DASS-21=Depression, Anxiety and Stress Scale-21 Item; FSCRS-SC=Forms of Self Criticising/Attacking and Self-Reassurance Scale-Self-Criticism; FSCRS-RS, Forms of Self Criticising/Attacking and Self-Reassurance Scale-Reassured Self; FoReST PI= Flexibility of Responses to Self-Critical Thoughts Scale-Psychological Inflexibility.

***p<0.001

Multiple Hierarchical Regression

A hierarchical regression was used to assess the ability of self-criticism (FSCRS Inadequate Self), self-reassurance (FSCRS Self-Reassurance) and psychological inflexibility (FoReST) to predict additional variance in emotional distress in people with TBI, beyond demographic and injury-related factors. Results from the assumption testing for multiple hierarchical regression are presented in Appendix D. All residuals appeared independent as indicated by a Durbin Watson statistic of 2.17. The relationship between the dependent variable (DASS-21 Total) and each independent variable, and the relationship between the dependent variable and the independent variables collectively both appeared to be linear. There was assumed to be homoscedasticity as assessed visually. There was no indication of multicollinearity between continuous variables, with all variable inflation values (VIFs) below 0.1 and tolerance values below 10. No significant outliers, high leverage or influential points were identified and residuals were identified as normally distributed as assessed visually.

In step 1, demographic variables accounted for approximately 3% of the variance in DASS-21 Total scores (Adjusted R^2=.03, F(5, 106)=1.71, p=0.137). With the addition of injury-related factors in step 2, an additional 16% of variance was explained. Demographic and injury-related factors therefore accounted for approximately 19% (Adjusted R^2=.19, F(6, 100)=4.44, p=0.001). In this model, self-reported cognitive symptoms (EMQ) made a significant independent contribution to the model. The addition of self-criticism (FSCRS-

SC), self-reassurance (FSCRS Reassured) and psychological inflexibility (FoReST) accounted for an additional 32% of variance in emotional distress, with the model Step 3 accounting for a total of 51% of variance (Adjusted R^2=.51, $F(3, 97)$=23.08, p<0.001). However, only self-criticism had a significant independent contribution in this model. Step 4 revealed no indirect effect of self-reassurance and psychological inflexibility on emotional distress through the interaction with self-criticism.

Table 4. Hierarchical regression analysis for predicting emotional distress (DASS-21 Total)

Model	**ΔAdjusted R^2**	**Δ*F***	***p***	**b (95% CI)**	**β**	***p***
Step 1	.03	1.72	.137			
Age (years)				-.19 (-.40, .12)	-.17	.081
Female				1.06 (-3.98, 6.11)	.04	.677
Higher education				-4.00 (-9.03, 1.03)	-.16	.117
Psychiatric history				4.85 (-.78, 10.49)	.17	.091
Time since injury				.13 (-.06, .32)	.13	.191
Step 2	.19	4.44	.001			
Age (years)				-.16 (-.36, .04)	-.15	.105
Gender: female				-.24 (-5.04, 4.57)	.01	.923
Higher education				-3.77 (-8.52, .98)	-.15	.118
Psychiatric history				1.40 (-4.16, 6.96)	.05	.618
Time since injury				.08 (-.10, .26)	.08	.373
Severity: moderate				.33 (-5.86, 6.53)	.01	.915
Severity: severe				-3.13 (-8.36, 2.09)	-.12	.237
EMQ*				.25 (.08, .43)	.28	.005
BPI Severity				.17 (-.08, .42)	.13	.190
FSS				.16 (-.01, .33)	.18	.068
Litigation				-.71 (-5.44, 4.02)	-.03	.767
Step 3	.51	23.08	<.001			
Age (years)				-.04 (-.20, .12)	-.04	.601
Gender: female				-.69 (-4.44, 3.05)	-.03	.716
Higher education				-3.56 (-7.30, .19)	-.14	.062
Psychiatric history				.70 (-3.62, 5.03)	.02	.748
Time since injury				.04 (-.10, .18)	.04	.584
Severity: moderate				-.64 (-5.47, 4.18)	-.02	.792
Severity: severe				-4.95 (-9.05, -.86)	-.18	.018
EMQ				.10 (-.05, .24)	.11	.189
BPI Severity				.06 (-.14, .26)	.05	.572
FSS*				.14 (-.01, .27)	.16	.043
Litigation				.54 (-3.23, 4.30)	.02	.778
FSCRS SC				.40 (.20, .61)	.41	<.001
FSCRS RS				-.25 (-.56, .05)	-.14	.103
FoReST PF				.15 (.02, .32)	.17	.079
Step 4	.50	.22	.804			
Age (years)				-.04 (-.20, .12)	-.04	.636

Gender: female	-.66 (-4.48, 3.14)	-.03	.729
Higher education	-3.55 (-7.32, -.23)	-.14	.065
Psychiatric history	.54 (-3.91, 4.98)	.02	.811
Time since injury	.04 (-.11, .18)	.03	.626
Severity: moderate	-.95 (-5.98, 4.07)	-.03	.707
Severity: severe	-5.08 (-9.24, -.93)	-.19	.017
EMQ	.09 (-.05, .24)	.11	.211
BPI Severity	.06 (-.14, .27)	.05	.537
FSS	.14 (.01, .28)	.16	.041
Litigation	.51 (-3.30, 4.32)	.02	.791
FSCRS SC	.39 (.18, .60)	.39	<.001
FSCRS RS	-.29 (-.61, .04)	-.16	.083
FoReST PF	.15 (-.02, .32)	.17	.082
FSCRS SC x FSCRS RS	-.01 (-.02, .01)	.05	.550
FSCRS SC x FoReST PI	<-.01 (-.01, .01)	-.03	.692

EMQ=Everyday Memory Questionnaire; BPI=Brief Pain Inventory; FSS=Fatigue Severity Scale; FSCRS-SC=Forms of Self-Criticising/Attacking and Self-Reassurance Scale- Self Criticism; FSCRS-RS= Forms of Self-Criticising/Attacking and Self-Reassurance Scale- Reassured Self; FoReST PI= Flexibility of Responses to Self-Critical Thought Scale- Psychological Inflexibility.

DISCUSSION

To the author's knowledge, this is the first study to explore the contribution of self-criticism, self-reassurance and psychological inflexibility to levels of emotional distress in people with TBI. Levels of emotional distress reported by participants in this sample appeared elevated compared with published normative data[49]. Consistent with previous literature[5,6,60], this provides additional evidence that people with TBI have an increased risk of experiencing psychological difficulties.

Initial correlations indicated that higher levels of emotional distress were associated with higher levels of self-criticism, higher levels of psychological inflexibility and lower levels of self-reassurance and therefore supported the first hypothesis.

Within the multiple regression analysis, overall, 51% of variance in emotional distress could be explained by demographic, injury-related and psychological constructs. The addition of self-criticism, self-reassurance and psychological inflexibility appeared to make the biggest contribution explaining an additional 32% of variance in emotional distress

beyond injury-related or clinical factors and therefore supported the second hypothesis. In this model (Step 3), self-criticism was the only construct to make an independent contribution. Self-reassurance and psychological inflexibility did not make a significant independent contribution, nor was there a significant interaction effect between these variables and self-criticism (Step 4). This final step did not support the third hypothesis predicting that self-reassurance and psychological inflexibility would moderate the relationship between self-criticism and emotional distress.

The results highlight the importance of self-criticism in understanding levels of emotional distress in people with TBI. This is something that has not been empirically tested previously. However, qualitative research has highlighted the role of shame and guilt in people with TBI[20,21] which appears in keeping with the present findings. It could be argued that significant life changes associated with a TBI, and the associated loss of potentially protective factors (e.g. employment and relationships) may potentially contribute to the strength of the relationship between self-criticism and emotional distress [2,3].

Whilst increasing self-reassurance and psychological flexibility (through the use of 'third wave' therapies such as CFT and ACT respectively) is purported to reduce distress associated with self-criticism, the current study found that neither reassurance, nor psychological flexibility, had either a significant direct or indirect effect on levels of emotional distress. Future longitudinal research is required to determine if changes in self-reassurance and/or psychological flexibility are associated with changes in distress.

Although previous research has highlighted the role of demographic factors contributing to psychological outcomes in people with TBI[7-9], the present findings appear inconsistent in that demographic factors alone (Step 1) did not predict levels of emotional distress.

The clinical factors (Step 2) assessed in the current study appeared to be more effective in predicting levels of emotional distress. Previous research exploring the association between psychological outcomes and pain, fatigue and cognitive functioning has yielded mixed results[12-15]. In the present study, only self-reported cognitive complaints (EMQ) made a significant independent contribution when all injury-related factors were entered into the model.

Limitations

There are a number of limitations to the present study. Firstly, as the study design is cross-sectional, causality cannot be assumed. In addition, despite the regression model being significant, there remains a large proportion of variance that was not explained. Therefore, there are likely to be additional factors, beyond those explored in the present study, that contribute to emotional distress in people with TBI. The present study does not include systemic factors, such as changes in employment status[2] and social relationships[3,59], which are widely recognised as indirect consequences of brain injury and are likely to impact on psychological outcomes. Additionally, information regarding social economic status and location of injury was not collected and therefore not included in the present analysis. It may be that, should these factors have been included, a more robust model explaining a larger proportion of variance may have been identified.

The data collected in the present study consisted solely on self-report measures. This relies on individuals to accurately report the details of their injury and to assess each domain they are responding to. Due to the design of the study, demographic and injury-related factors such as injury severity (as measured by duration of loss of consciousness), nature of injury and time since injury could not be verified and were dependent on individuals' retrospective reporting. Additionally, self-report measures are vulnerable to bias. This may be particularly true of the self-criticism and self-reassurance scales used in the current study that derived

from the same scale, and therefore may be more correlated due to similar wording and timing of included items.

Despite achieving adequate power for the regression analysis, the present study includes a relatively small sample of people with TBIs. Furthermore, people with TBI are often considered a heterogeneous population as there are a plethora of symptoms and difficulties that are reported in this population. Within the present study, there was variation regarding the nature of injuries with the majority of people sustaining a TBI due to road traffic accidents. A small proportion (12%) of participants reported non-traumatic brain injuries, such as stroke or encephalitis, however it was unclear whether these were secondary to TBI. A larger sample size would allow for further exploration of various subgroups, which may be stratified by nature and severity of injury. Additionally, a larger sample size would allow for alternative statistical modelling analyses such as structural equation modelling, which are often considered more robust and may provide a more in depth picture of the unique role of psychological constructs and emotional distress in people with TBI.

The present study recruited participants from a variety of sources including a hospital, rehabilitation settings, national charity organisations and online social media support groups. It was not possible to identify where participants were recruited from due to the design of the questionnaire. Therefore, potential differences in outcomes, depending on where participants were recruited from could not be explored. It was also noted that all participants who took part were actively engaged in help seeking, whether it be from online support groups, charities or healthcare services. Many people who sustain a mild TBI are likely to make a full recovery with little or no intervention and therefore, there is likely to be a proportion of people with TBI who do not continue contact with services or support groups. Therefore, people who do not seek support following TBI are likely to be under represented in the present study.

Whilst there are a number of limitations, the present study also has a number of strengths. A considerable number of demographic and injury-related factors, which have been indicated as impacting on psychological outcomes in previous research, were included in the multiple regression analysis. This provides a robust exploration of whether the psychological constructs predicted levels of emotional distress, even when controlling for demographic and injury related factors. This allows to clearer evaluation of the contribution of psychological constructs.

Similarly, the present study is the first to quantitatively explore the role of self-criticism in people with TBI. Whilst previous qualitative literature has highlighted the role of shame and guilt, the present study highlights the process of self-criticism and how this relates to the experience of emotional distress. Unlike injury-related factors, which may be a direct result of structure damage to the brain, psychological processes may be more amenable to change and therefore provide promising theoretical grounding for psychological therapies being effective treatments for reducing emotional distress.

Clinical Implications

The present research provides further evidence for elevated emotional distress in people with TBI and highlights the importance of providing psychological support for people experiencing such difficulties. Whilst there may be a temptation within clinical settings to focus on the cognitive and physical symptoms reported by many people with TBI, the present study highlights the importance of understanding psychological processes that may contribute to emotional distress. Similarly, effective identification of those most at risk may include screening of psychological processes, particularly measures of self-criticism.

The present study is the first to explore the relationship between self-criticism and self-reassurance and emotional distress in people who have sustained a TBI. The findings indicate that higher self-criticism is associated with increased levels of emotional distress,

even when controlling for many demographic and injury related factors. Psychological processes are often more modifiable than demographic of injury-related factors, specifically those caused directly by damage to the brain. Therefore, targeting self-criticism in psychological interventions may lead to more effective support for those experiencing significant emotional distress following TBI.

Further Research

Whilst self-criticism, self-reassurance and psychological inflexibility explained an additional 30% of variance in emotional distress than demographic and injury-related factors alone, there remains a considerable degree of variance in distress unexplained. Further exploration of the key factors, including psychological processes which underlie the development and maintenance of emotional distress following TBI, will allow for more effective identification of those at risk of poor psychological outcomes and may guide development of appropriate intervention.

Although being adequately powered, the present study includes a relatively small sample of people with TBI. Replication of the current findings utilising a longitudinal design to determine how changes in self-criticism, self-reassurance and psychological inflexibility are associated with changes in distress across time.

Research has consistently demonstrated that people with TBI experience elevated levels of psychological difficulties and emotional distress[7-9], whilst evidence for effective psychological interventions remains limited[25]. Future research should continue to evaluate how existing therapy models (CBT and 'third-wave' approaches) compare with appropriate control groups. Different psychotherapy interventions that demonstrate good efficacy for reducing psychological distress in people with TBI relative to control groups can then be compared with each other via clinical trials to determine which approaches are superior for reducing distress in people with TBI.

Conclusion

In summary, the present study highlights the role of psychological factors, specifically those relating to personal evaluation in understanding levels of emotional distress in people with TBI. It is common for professionals supporting people following TBI to target the physical and cognitive sequelae as they are often easily observed. Emotional difficulties, on the other hand, may be less immediately apparent and/or seen as secondary to physical and neurocognitive factors. Whilst the present study found that clinical factors may be significant predictors of emotional distress, particularly with self-reported cognitive functioning, self-criticism appeared to explain the largest proportion of variance. After controlling for many demographic and injury-related factors, self-criticism explained an additional 30% of variance in emotional distress. Therefore, self-criticism should be a specific treatment target for therapies supporting people experiencing emotional distress following TBI. It is acknowledged that different approaches may target self-criticism in different ways with traditional CBT approaches challenging the content and third wave therapies aiming to change the relationship one has with self-criticism. Whilst the present study does not specifically support CFT and ACT approaches, it demonstrates that psychological processes significantly contribute to levels of emotional distress, beyond demographic and injury related factors. This is promising in that psychological processes are more amenable to change and therefore levels of emotional distress could be improved through psychological therapies focusing on these processes. Through longitudinal research, psychological therapies including third wave therapies, can be better evaluated to assess clinical effectiveness for people with TBIs who are experiencing significant levels of emotional distress. Third wave therapies, such as ACT and CFT, are likely to be important approaches for people whose self-criticism may be valid to their situation, such as “my memory isn’t as good as it used to be”, and therefore challenging the content would be inappropriate. Changing the relationship one

has with their self-criticism, through developing self-reassurance or psychological flexibility, may in turn reduce the intensity or frequency of self-criticism.

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List of Appendices

Appendix A – Author Guidelines for the Journal of Neurotrauma

MANUSCRIPTS

GENERAL INSTRUCTIONS

Full mailing information should be included if not on title page, then the following page. Corresponding author should be identified on title page. Prepare text double-spaced throughout. Leave ample margins on sides, top and bottom of the page. Please submit text in Microsoft Word. On the first page, give the full title of the paper, **full name(s) and institutional affiliation(s)** of author(s) with the highest academic degrees and institutional titles. Provide a running title (<45 characters) and a Table of Contents title (<75 characters), if the full title is longer than these limits. **We require the full mailing address and contact information (**telephone, fax, and e-mail address) for EACH author listed on your article. Please include the address (es). **Please also indicate the corresponding author.** Supply an abstract (<250 words) which presents the reasons for the study, the main findings (with specific data), the principal conclusions, and a list of key words (maximum of 5). Original research papers should contain the following sections: introduction, materials and methods, results, discussion, acknowledgments, references, tables, and figure legends. One subsection level is allowed. Short communications should be prepared similarly to original papers. Begin each section on a separate page.

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Journal of Neurotrauma **is updating its referencing style to the numbered reference system. All submitted manuscripts should be prepared according to this new style. Please see below for the revised instructions.**

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Bele, S., and Brawanski, A. (2009). Biomarkers and surrogate markers, in: *Neurotrauma and Critical Care of the Brain*. J. Jallo, and C.M. Loftus (eds). Theime Publishing: New York, pps. 42-52.

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Appendix B – Author Guidelines for Journal of Head Trauma Rehabilitation

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As of 2016, JHTR will accept brief reports that do not exceed 2000 words, 3 tables and/or figures and 15 references.

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Authors must state all possible conflicts of interest in the Title Page of the manuscript, including financial, consultant, institutional, and other relationships that might lead to bias or a conflict of interest. If there is no conflict of interest, this should also be explicitly stated as none declared. All relevant conflicts of interest and sources of funding should be included on the title page of the manuscript with the heading "Conflicts of Interest and Source of Funding:". For example:

Conflicts of Interest and Source of Funding: Author A has received honoraria from Company Z. Author B is currently receiving a grant (#12345) from Organization Y and is on the speaker's bureau for Organization X—the CME organizers for Company A. For the remaining authors none were declared.

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- Manuscripts should be line numbered in their original format (eg, Microsoft Word line numbering).
- Manuscripts should be double-spaced, including quotations, lists, references, footnotes, figure captions, and all parts of tables. Do not embed tables in the text.
- Manuscripts should be ordered as follows: title page, abstracts, text, references, appendices, tables, and any illustrations.
- To maintain a masked review process, it is the author's responsibility to make every attempt to mask all information in the manuscript that would reveal the identity of the

author to the reviewer. This version of the manuscript is referred to as the "masked" manuscript when uploading documents.

- An accompanying cover letter should include attestations that (1) the work is original and has not been published or under review elsewhere; (2) all authors contributed to the work; and (3) the research was conducted consistent with ethical guidelines for the conduct of research.
- The cover letter should also summarize any conflicts of interest affecting any authors.
- Title page including (1) title of the article; (2) author names (with highest academic degrees) and affiliations (including titles, departments, and name and location of institutions of primary employment); (3) all possible conflicts of interest including financial, consultant, institutional, and other relationships that might lead to bias or a conflict of interest; (4) disclosure of funding received for this work including from any of the following organizations with public or open access policies: National Institutes of Health (NIH), National Institute on Disability Independent Living and Rehabilitation Research, Veterans Administration, Wellcome Trust, and the Howard Hughes Medical Institute; and (5) any acknowledgments, credits, or disclaimers.
- A structured abstract of no more than 200 words should be prepared. Authors should use telegraphic language where possible, including omission of introductory clauses. Headings should typically include the following: Objective, Setting, Participants, Design, Main Measures, Results, and Conclusion. The Conclusion section should encapsulate the clinical implications of the resul
- ts, not merely restate the findings.
- Include up to 10 key words that describe the contents of the article such as those that appear in the Cumulative Index to Nursing and Allied Health Literature (CINAHL) or the National Library of Medicine's (NLM's) Medical Subject Headings (MeSH).
- There should be a clear indication of the placement of all tables and figures in text.
- The author is responsible for obtaining written permission for any borrowed text, tables, or figures.

References

- References must be cited in text and styled in the reference list according to the *American Medical Association Manual of Style*, 10th edition, copyright 2007 American Medical Association. They must be numbered consecutively in the order they are cited and listed in that sequence (not alphabetically); reference numbers may be used more than once throughout an article. Page numbers should appear with the text citation following a specific quote. References should be double-spaced and placed at the end of the text.
- References should not be created using Microsoft Word's automatic footnote/endnote feature.

Figures

A. Four Steps for Submitting Artwork

1. Learn about Digital Art creation here.

2. Create, Scan, and Save your artwork according to the Digital Artwork Guideline Checklist.
3. Upload each figure to Editorial Manager in conjunction with your manuscript text and tables.

B. Color Figures: The journal accepts color figures for publication that will enhance an article. Authors who submit color figures will receive an estimate of the cost for color reproduction in print. If they decide not to pay for color reproduction in print, they can request that the figures be converted to black and white at no charge. All color figures can appear in color in the online version of the journal at no charge. (Note: this includes the online version on the journal website and Ovid, but not the iPad edition currently.)

C. Digital Artwork Guideline Checklist Basics to have in place before submitting your digital art.

- Artwork saved as JPG, TIFF and EPS files. Do not save TIFFs as compressed files.
- Artwork created as the actual size (or slightly larger) than it will appear in the journal. (To get an idea of the size images should be when they print, study a copy of the journal. Measure the artwork typically shown and scale your image to match.)
- Crop out any white or black space surrounding the image.
- Text and fonts in any figure are one of the acceptable fonts: Helvetica, Times Roman, Symbol, Mathematical PI, and European PI.
- Color images are created/scanned and saved and submitted as CMYK only. Do not submit any figures in RGB mode because RGB is the color mode used for screens/monitors and CMYK is the color mode used for print.
- Line art saved at a resolution of at least 1200 dpi.
- Images saved at a resolution of at least 300 dpi.
- Each figure saved as a separate file and saved separately from the accompanying text file.
- For multipanel or composite figures only: Any figure with multiple parts should be sent as one file, with each part labeled the way it is to appear in print.

Remember:

- Artwork generated from office suite programs such as CorelDRAW, MS Word, Excel, and artwork downloaded from the Internet (JPEG or GIF files) cannot be used because the quality is poor when printed.
- Cite figures consecutively in your manuscript.
- Number figures in the figure legend in the order in which they are discussed.
- Upload figures consecutively to the Editorial Manager Web site and number figures consecutively in the Description box during upload.
- All electronic art that cannot be successfully uploaded must be submitted on a 31/2-inch high-density disk, a CD-ROM, or an Iomega Zip disk, accompanied by high-resolution laser prints of each image.

Tables Tables should be on a separate page at the end of the manuscript. Number tables consecutively and supply a brief title for each. Include explanatory footnotes for all

nonstandard abbreviations. Cite each table in the text in consecutive order. If you use data from another published or unpublished source, obtain permission and acknowledge fully.

Supplemental Digital Content Authors may submit SDC that enhances their article's text to be considered for online posting. SDC may include standard media such as text documents, graphs, audio, video, etc. On the Attach Files page of the submission process, please select Supplemental Audio, Video, or Data for your uploaded file as the Submission Item. If an article with SDC is accepted, our production staff will create a URL with the SDC file. The URL will be placed in the call-out within the article. SDC files are not copyedited by LWW staff; they will be presented digitally as submitted. For a list of all available file types and detailed instructions, please visit the Checklist for Supplemental Digital Content.

SDC Call-outs: SDC must be cited consecutively in the text of the submitted manuscript. Citations should include the type of material submitted (Audio, Figure, Table, etc.), be clearly labeled as "Supplemental Digital Content," include the sequential list number and provide a description of the supplemental content. All descriptive text should be included in the call-out, as it will not appear elsewhere in the article.
Example:
We performed many tests on the degrees of flexibility in the elbow (see Video, Supplemental Digital Content 1, which demonstrates elbow flexibility) and found our results inconclusive.

List of Supplemental Digital Content: A listing of SDC items must be submitted at the end of the manuscript file. Include the SDC number and file type. This text will be removed by our production staff and not be published.
Example:
Supplemental Digital Content 1. wmv

SDC File Requirements: All acceptable file types are permissible up to 10 MB. For audio or video files greater than 10 MB, authors should first query the journal office for approval. For a list of all available file types and detailed instructions, please visit the Checklist for Supplemental Digital Content.

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An author whose work is funded by an organization that mandates the use of the Creative Commons Attribution (CC BY) license is able to meet that requirement through the available open access license for approved funders. Information about the approved funders can be found here: http://www.wkopenhealth.com/inst-fund.php

FAQ for open access
http://www.wkopenhealth.com/openaccessfaq.php

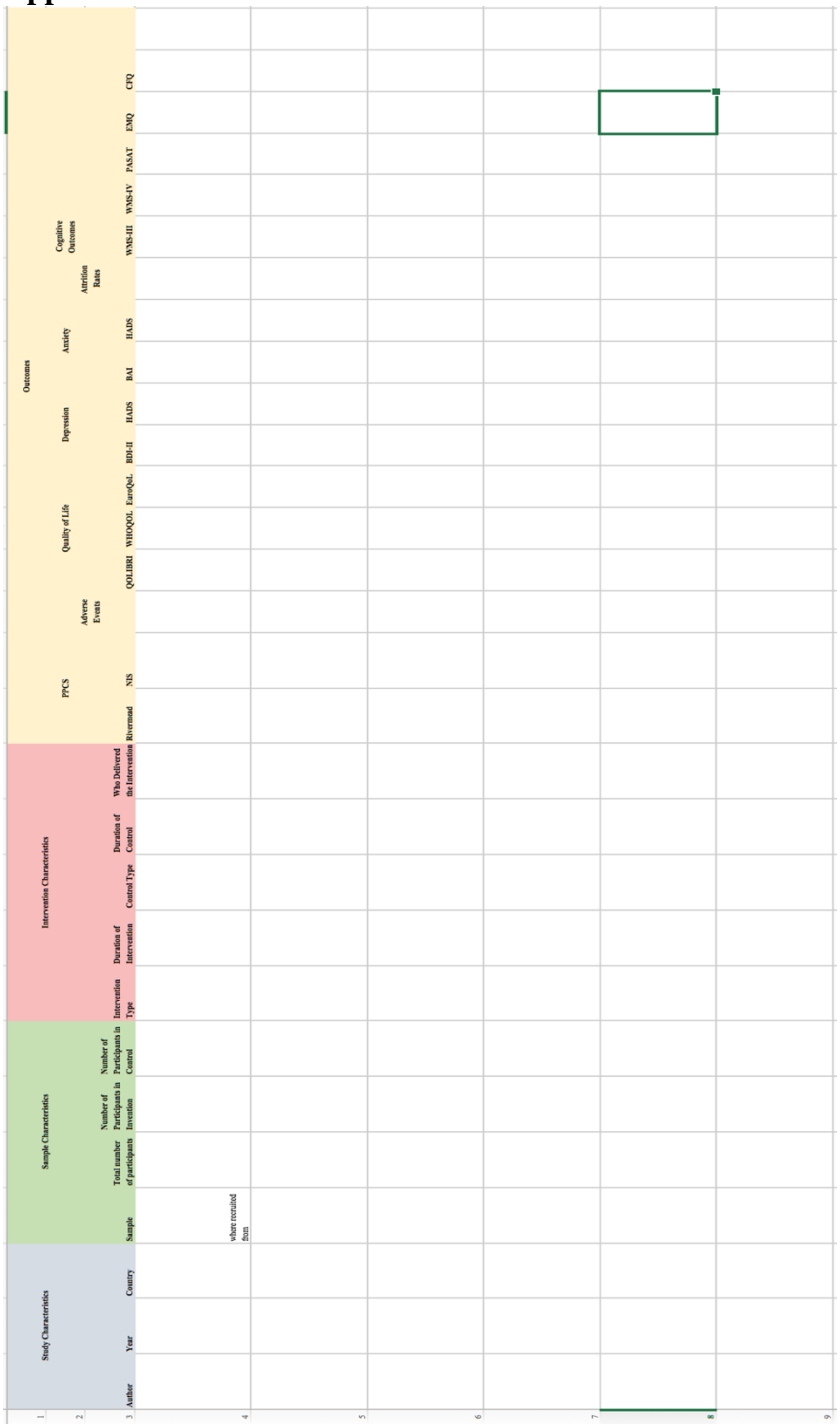
Appendix C – Systematic Review Search Strategy

Concept	**Search Terms**		
	Medline terms	*PsycInfo terms*	*Scopus terms*
Brain Injury	Exp Brain Injury/ Exp Brain Concussion/ Exp PostConcussion Syndrome/	Exp Brain Concussion/ Exp Traumatic Brain Injury/	Exp brain Concussion/ Exp brain Injury/ Exp postconcussion syndrome/

	Concussion.ti.ab "brain damage".ti.ab "brain injur*".ti.ab "head injur*".ti.ab "post concussion".ti.ab "postconcussion".ti.ab "post-concussion".ti.ab mtbi.ti.ab pcs.ti.ab		
Psychological therapy	Exp Behavior Therapy/ Exp Cognitive Therapy/ Exp Psychotherapy/ Exp Rehabilitation/	Exp Behavioral Therapy/ Exp Cognitive Therapy/ Exp PSYCHOTHERAPY/ Exp REHABILITATION/	Exp behaviour therapy/ Exp cognitive therapy/ Exp psychotherapy/ Exp cognitive rehabilitation/
	"cognitive behaviour therap*".ti.ab "cognitive behavior therap*".ti.ab "cognitive therap*".ti.ab "psychoeducation*".ti.ab "psychological intervention*".ti.ab "psychological therap*".ti.ab "psychological treatment*".ti.ab CBT.ti.ab Minfullness*.ti.ab "cognitive rehabilitat*".ti.ab Relaxation*.ti.ab		

**Please MESH terms are indicated by the 'exp' function.*

Appendix D – Data Extraction Form



Appendix E – Power Calculation (a priori and sensitivity)

An *a priori* sample size calculation was completed using G*Power (Faul & Erdfelder, 2009). Using, 80% power and 16 predictor variables (to account for dummy variables), a sample size of 91 was identified as sufficiently powered to identify an effect size of 0.25. A sensitivity power calculation was also completed, which revealed that the sample size of 118 was sufficiently powered to identify an effect size of just over 0.18, with 80% power and an alpha value of 0.05.

Appendix F – Research Review Committee Approval

D.Clin.Psychology Programme
Division of Clinical Psychology
Whelan Building, Quadrangle
Brownlow Hill
LIVERPOOL
L69 3GB

Tel: 0151 794 5530/5534/5877
Fax: 0151 794 5537
www.liv.ac.uk/dclinpsychol

Cerian Jackson
Clinical Psychology Trainee
Doctorate of Clinical Psychology Doctorate Programme
University of Liverpool
L69 3GB

20 September 2017

RE: Investigating the impact of self-compassion on the experience of distress in people with traumatic brain injuries
Trainee: Cerian Jackson
Supervisors: Ross White & Perry Moore

Dear Cerian,

Thank you for your notification of minor amendment to your proposal submitted to the Chair of the D.Clin.Psychol. Research Review Committee (*dated 29/08/17*).

I can now confirm that your amended proposal (*version number 2, dated 23/08/17*) meets the requirements of the committee and has been approved by the Committee Chair.

Please take this Chairs Action decision as ***final*** approval from the committee.

You may now progress to the next stages of your research.

I wish you well with your research project.

Dr Catrin Eames
Vice-Chair D.Clin.Psychol. Research Review Committee.

Appendix G – Research Review Committee Amendment Approval

11/12/17

Dear RRC Chair,

I am writing regarding a proposed amendment to my DClin research project proposal (version 2, 23/08/17).

The proposed amendment and rationale for this amendment are detailed in the table below:

Amendment	Rationale
The proposed amendment is to remove the Self-Compassion Scale (SCS; Neff 2003) and to add a Flexibility of Responses to Self-Critical Thoughts Scale (FoReST; White et al., in submission). The SCS is a 26-item self report questionnaire measuring individuals self compassion and the FoReST is a 12 item self-report questionnaire measuring psychological flexibility.	The reason for this proposed change is due to the identification of a condsiderable overlap between the SCS and another measure (Forms of Self-Attacking/Self-Reassurance; Gilbert, 2004). This also impacts the secondary aim of an exploratory analysis looking at the relationship between self-criticism, compassion and emotional distress. Exploring the additional role of psychological flexibility around self-criticism as measured by the FoReST (White et al., in submission) would allow for a secondary exploratory analysis exploring the relationship between self-criticism/self-reassurance and psychological flexibility in relation to emotional distress.

Please note that the SCS and the FoReST are free measures therefore there are no amendments to the proposed budget for this project.

The proposed amendment has been included in the revised version of the research proposal that I have forwarded for your consideration (version 3, 07/12/17).

Kind regards,

Cerian Jackson
Trainee Clinical Psychologist
University of Liverpool

Signatures

Dr Ross White (Primary Supervisor)
12th Dec 2017

Dr Perry Moore (Secondary Supervisor)

Appendix H – University of Liverpool Sponsorship Approval

Dr Ross White
MRC North West Hub for Trials Methodology Research
Institute of Psychology, Health and Society
Block B, Waterhouse Building
Brownlow Hill
Liverpool
L69 3GB

Mr Alex Astor
Head of Research Support – Health and Life Sciences

University of Liverpool
Research Support Office
2nd Floor Block D Waterhouse Building
3 Brownlow Street
Liverpool
L69 3GL

Tel: 0151 794 8739
Email: sponsor@liv.ac.uk

15 March 2018

Sponsor Ref: UoL001327

Re: Sponsor Permission to Proceed notification

"Investigating the impact of self-compassion on the experience of distress in people with traumatic brain injuries"

Dear Dr Ross White

All necessary documentation and regulatory approvals have now been received by the University of Liverpool Research Support Office in its capacity as Sponsor, and we are satisfied that all Clinical Research Governance requirements have been met. You may now proceed with any study specific procedures to open the study.

The following REC Approved documents have been received by the Research Support Office. Only these documents can be used in the recruitment of participants. If any amendments are required please contact the Research Support Office.

Document title	Version	Date
Protocol	4	14th December 2017
Participant Consent Form	2	14th December 2017
Participant Information Sheet	2	14th December 2017
Validated Questionnaire (FoReST)	No version	No date
Advertisement	2	24th October 2017
Non-validated Questionnaire (Demographic Questionnaire)	1	26th June 2017
Validated Questionnaire (QOLIBRI)	No version	No date
Validated Questionnaire (Brief Pain Inventory)	No version	No date
Validated Questionnaire (Fatigue Severity Scale)	No version	No date
Validated Questionnaire (Everyday Memory Questionnaire)	No version	No date
Validated Questionnaire (DASS-21)	No version	No date
Validated Questionnaire (Forms of Self-criticism)	No version	No date

TEM013 UoL Permission to Proceed notification
Version 6.00 Date 18/08/2017

Page **1** of **2**

Please note, under the terms of your Sponsorship you must;

1. Gain Site Permission from each participating site before recruitment begins at that site;
2. Ensure all required contracts are fully executed before recruitment begins at any site;
3. Inform the Research Support Office as soon as possible of any adverse events especially SUSARs and SAE's, Serious Breaches to protocol or relevant legislation or any concerns regarding research conduct (as per *SOP007 and SOP017)*;
4. Approval must be gained from the Research Support Office for any amendments to, or changes of status in the study **prior to** submission to REC and any other regulatory authorities (as per SOP018);
5. It is a requirement that Annual Progress Reports are sent to the NHS Research Ethics Committee (REC) annually following the date of Favourable Ethical Approval. You must provide copies of any reports submitted to REC and other regulatory authorities to the Research Support Office (as per SOP006);
6. Maintain the study master file (as per SOP005);
7. Make available for review any study documentation when requested by the sponsors and regulatory authorities for the purposes of audit or inspection;
8. Upon the completion of the study it is a requirement to submit an End of Study Declaration (within 90 days of the end of the study) and End of Study Report to REC (within 12 months of the end of the study). You must provide copies of this to the Research Support Office (as per SOP021);
9. Ensure you and your study team are up to date with the current RSO SOPs throughout the duration of the study.

If you have any queries regarding the sponsorship of the study please do not hesitate to contact the Clinical Research Governance Team on 0151 794 8373 (email sponsor@liv.ac.uk).

Yours sincerely

Mr Alex Astor
Head of Research Support – Health and Life Sciences
Research Support Office

TEM013 UoL Permission to Proceed notification
Version 6.00 Date 18/08/2017

Page **2** of **2**

Mr Alex Astor
Head of Research Support – Health and Life Sciences
Research Support Office

Appendix I – Research Ethics Committee (REC) Approval

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

Dr Ross White
Department of Clinical Psychology
Whelan Building
University of Liverpool
L69 3GQ

West of Scotland REC 5
West of Scotland Research Ethics Service
West Glasgow Ambulatory Care Hospital
Dalnair Street
Glasgow
G3 8SJ

Date 29 November 2017

Direct line 0141 232 1809
E-mail WoSREC5@ggc.scot.nhs.uk

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

Dear Dr White

Study title:	**Investigating the impact of self-compassion on the experience of distress in people with traumatic brain injuries**
REC reference:	**17/WS/0232**
Protocol number:	**UoL001327**
IRAS project ID:	**233411**

Thank you for responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of

the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" above).

Approved documents

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Advertisement]	2	24 October 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Clinical Trials Insurance 2017-2018]		27 July 2017
IRAS Application Form [IRAS_Form_25102017]		25 October 2017
Letter from funder [Approval RRC]		20 October 2017
Letter from sponsor [Sponsor Letter]		04 October 2017
Non-validated questionnaire [Demographic questionnaire]	1.0	26 June 2017
Other [Response to REC]		
Participant consent form [Consent form Complete]	1	23 June 2017
Participant information sheet (PIS) [PIS Complete v2]	2	15 November 2017
Research protocol or project proposal [Protocol A Combined]	2	23 August 2017
Summary CV for Chief Investigator (CI) [RW Curriculum Vitae - Brief]		
Summary CV for student [CV]	1	09 October 2017
Summary CV for supervisor (student research) [RW Curriculum Vitae - Brief]	1	09 October 2017
Summary CV for supervisor (student research) [CV Perry Moore 2017]		
Validated questionnaire [QOLIBRI]		
Validated questionnaire [Brief Pain Inventory]		
Validated questionnaire [Fatigue Severity Scale]		
Validated questionnaire [Everyday Memory Questionnaire]		
Validated questionnaire [DASS-21]		
Validated questionnaire [Self-compassion SF]		
Validated questionnaire [Forms of Self-criticism]		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance

We are pleased to welcome researchers and R & D staff at our RES Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

17/WS/0232	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

SMacgregor

for
Canon Matt McManus
Chair

Enclosures: "After ethical review – guidance for researchers"

Copy to: Mr Alex Astor, University of Liverpool
Mr Dave Watling, The Walton Centre NHS Foundation Trust
Ms Cerian Jackson, University of Liverpool

Mr Alex Astor
Head of Research Support – Health and Life Sciences
Research Support Office

Appendix J – Research Ethics Committee (REC) Amendment Approval

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

West of Scotland REC 5
West of Scotland Research Ethics Service
West Glasgow Ambulatory Care Hospital
Dalnair Street
Glasgow
G3 8SJ

Date 20 December 2017

Direct line 0141 232 1809
E-mail WoSREC5@ggc.scot.nhs.uk

Ms Cerian Jackson
Department of Clinical Psychology
Whelan Building
L69 3GQ

Dear Ms Jackson

Study title: **Investigating the impact of self-compassion on the experience of distress in people with traumatic brain injuries**
REC reference: **17/WS/0232**
Protocol number: **UoL001327**
Amendment number: **1**
Amendment date: **14 December 2017**
IRAS project ID: **233411**

Thank you for submitting the above amendment, which was received in full on 20 December 2017. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the Sub-Committee of the REC at its next meeting.

Documents received

The documents to be reviewed are as follows:

Document	*Version*	*Date*
Notice of Substantial Amendment (non-CTIMP)	1	14 December 2017
Participant consent form	2	14 December 2017
Participant information sheet (PIS)	2	14 December 2017
Research protocol or project proposal	4	14 December 2017
Validated questionnaire		

Notification of the Committee's decision

The Committee will issue an ethical opinion on the amendment within a maximum of 35 days from the date of receipt.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval for the research.

We are pleased to welcome researchers and R & D staff at our Research Ethics Service Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

17/WS/0232:	Please quote this number on all correspondence

Yours sincerely

Sharon Macgregor
REC Manager

Copy to: Mr Dave Watling, The Walton Centre NHS Foundation Trust
Dr Ross White, University of Liverpool

Appendix K – Documentation of Capacity and Capability (The Walton Centre NHS Foundation Trust)

Dear Cerian,

Study title:	**Investigating the impact of self-compassio experience of distress in people with trau injuries**
REC reference:	**17/WS/0232**
Protocol number:	**UoL001327**
IRAS project ID:	**233411**

This email confirms that The Walton Centre NHS Foundation Trust has the capacity and capability to deliver the above referenced study.

Please note that although this study has been accepted for commencement at The Walton Centre, you will not be able to recruit into the study until our site has been activated by the sponsor.

Please print this email and file in site file:

Thanks
Dave Watling. R.G.N.
Neuroscience Research Centre Manager.
Telephone 0151 556 3389.
Email dave.watling@thewaltoncentre.nhs.uk
The Walton Centre NHS Foundation Trust, Lower Lane, Liverpool, L9 7LJ

Appendix L – Health and Research Authority Approval

NHS
Health Research Authority

Dr Ross White
Department of Clinical Psychology
Whelan Building
University of Liverpool
L69 3GQ

Email: hra.approval@nhs.net

11 January 2018 *(Revised 17 January 2018 to include amendment 1 documents in document list)*

Dear Dr White

Letter of HRA Approval

Study title:	**Investigating the impact of self-criticism and self-reassurance on the experience of distress in people with traumatic brain injuries**
IRAS project ID:	**233411**
Protocol number:	**UoL001327**
REC reference:	**17/WS/0232**
Sponsor	**The University of Liverpool**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

IRAS project ID	233411

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from the HRA website.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators"*, issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found through IRAS.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application

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procedure. If you wish to make your views known please use the feedback form available on the HRA website.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details on the HRA website.

Your IRAS project ID is **233411**. Please quote this on all correspondence.

Yours sincerely

Simon Connolly
Senior Assessor

Email: hra.approval@nhs.net

Copy to: *Mr Alex Astor, The University of Liverpool*
Mr Dave Watling, The Walton Centre NHS Foundation Trust

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Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Advertisement]	2	24 October 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Clinical Trials Insurance 2017-2018]		27 July 2017
HRA Schedule of Events [Schedule of events]	1	09 October 2017
HRA Statement of Activities [Statement of activities v1]	1	12 October 2017
IRAS Application Form [IRAS_Form_25102017]		25 October 2017
Letter from funder [Approval RRC]		20 October 2017
Letter from sponsor [Sponsor Letter]		04 October 2017
Non-validated questionnaire [Demographic questionnaire]	1.0	26 June 2017
Notice of Substantial Amendment (non-CTIMP)	1	14 December 2017
Other [Response to REC]		
Participant consent form	2	14 December 2017
Participant information sheet (PIS)	2	14 December 2017
Research protocol or project proposal	4	14 December 2017
Summary CV for Chief Investigator (CI) [RW Curriculum Vitae - Brief]		
Summary CV for student [CV]	1	09 October 2017
Summary CV for supervisor (student research) [RW Curriculum Vitae - Brief]	1	09 October 2017
Summary CV for supervisor (student research) [CV Perry Moore 2017]		
Validated questionnaire [QOLIBRI]		
Validated questionnaire [Brief Pain Inventory]		
Validated questionnaire [Fatigue Severity Scale]		
Validated questionnaire [Everyday Memory Questionnaire]		
Validated questionnaire [DASS-21]		
Validated questionnaire [Forms of Self-criticism]		
Validated questionnaire [FoReST]		

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Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations, capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Dr Ross White
Tel: 01517948739
Email: Ross.White@liverpool.ac.uk

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	Statement of activities will form agreement between sponsor and participating NHS organisations.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study

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Section	HRA Assessment Criteria	Compliant with Standards	Comments
4.3	Financial arrangements assessed	Yes	Study forms part of doctorate qualification.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	Clarified that personal computers will not be used to hold study data.
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	Substantial amendment given favourable opinion 9 January 2018 included in approval.
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

There will be a single participating NHS organisation where potential participants will be approached. Participants will be asked to complete a set of questionnaires.
Participants will also be recruited outside the NHS. HRA approval does not cover research activities outside NHS organisations.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.

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If Chief Investigators, sponsors or Principal Investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the Chief Investigator, sponsor or Principal Investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.

Participating NHS organisations in England **will be expected to formally confirm their capacity and capability to host this research**.

- Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capacity will be confirmed is detailed in the *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* section of this appendix.
- The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).

There will be a principal investigator in place at the participating NHS organisation.

GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken

Where arrangements are not already in place, researchers completing research activities in NHS facilities will require a Letter of Access based on standard DBS checks and occupational health clearance.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.

- The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

Appendix M – Participant Information Sheet

The Walton Centre NHS
NHS Foundation Trust

UNIVERSITY OF LIVERPOOL

PARTICIPANT INFORMATION SHEET

Research Title Investigating the impact of self-criticism and self-reassurance on the experience of distress in people with traumatic brain injuries

Invitation: You are being invited to take part in the research project exploring the impact self-compassion in people who have sustained a traumatic brain injury. Before taking part, please carefully read through the information detailed in this document and discuss with others if you want. If you have any questions or wish to clarify any of this information please contact the researcher, Miss Cerian Jackson (details listed at the bottom of this document). Thank you for reading this.

What is the purpose of this project? Psychological difficulties are common following traumatic brain injury. This project aims to explore the impact of self-criticism and self-compassion on psychological distress in people who have sustained a traumatic brain injury. Results of the study may provide preliminary support for the potential clinical utility of additional psychotherapy approaches.

Why have I been chosen? You have been invited to take part as you have a history of traumatic brain injury.

Do I have to take part? It is up to you whether you wish to take part or not. If you wish to take part, please complete the online questionnaire. You may withdraw from the study at any time and your data will be removed from the study. Please note that it may not be possible to withdraw your data from the study once data analysis has commenced (scheduled April 2018)

What will happen to me if I take part? If you choose to take part in the project, you will be asked to complete a consent form indicating your consent to take part. Following this you will be asked to complete a questionnaire pack. It is estimated that this questionnaire pack will take approximately 25-35 minutes to complete. Where possible, you may be given the opportunity to complete an online version of the questionnaire pack.

What do I have to do? Please answer the questions in the online questionnaire. There are no other requirements for participating in this project. You will receive an email with a copy of this information and contact details of the researcher. When completing a hard copy questionnaire pack, you will be given a hard copy of this information, rather than receiving this via email.

What are the possible risks of taking part? It is not anticipated that participating in this research will cause any discomfort or disadvantage.

What are the possible benefits of taking part? In terms of immediate benefits of taking part, you will be entered into a prize draw in which 10 participants will win a £50 voucher. It is also hoped that the findings of the project will support the development of additional psychotherapy approaches for people following traumatic brain injuries.

What if something goes wrong? If you have any complaints about the project, please contact the researcher. If you do not believe your complaint has been handled to your satisfaction, please contact the Research Support Office at the University of Liverpool (details below).

Will my data be kept confidential? On completion of the online questionnaire, your data will be stored on QALTRICS, an online database only accessibly by the researchers. The researcher will remove all identifiable information from your data and your contact details will be stored on a separate database available only to the researchers. Contact details are used for the prize draw only unless you have indicated that you would like to be contacted for further research opportunities.

What type of information will be sought from me and why is the collection of this information relevant for the aims of the research? The questionnaire will ask you about your psychological experiences, mood, self-criticism, self-compassion and quality of life. The project will assess the interaction between these factors to determine how self-compassion and self-criticism may impact on psychological distress.

What will happen to the results of the research? Results of the research will be published. No participant identifiable information will be included in any published documents.

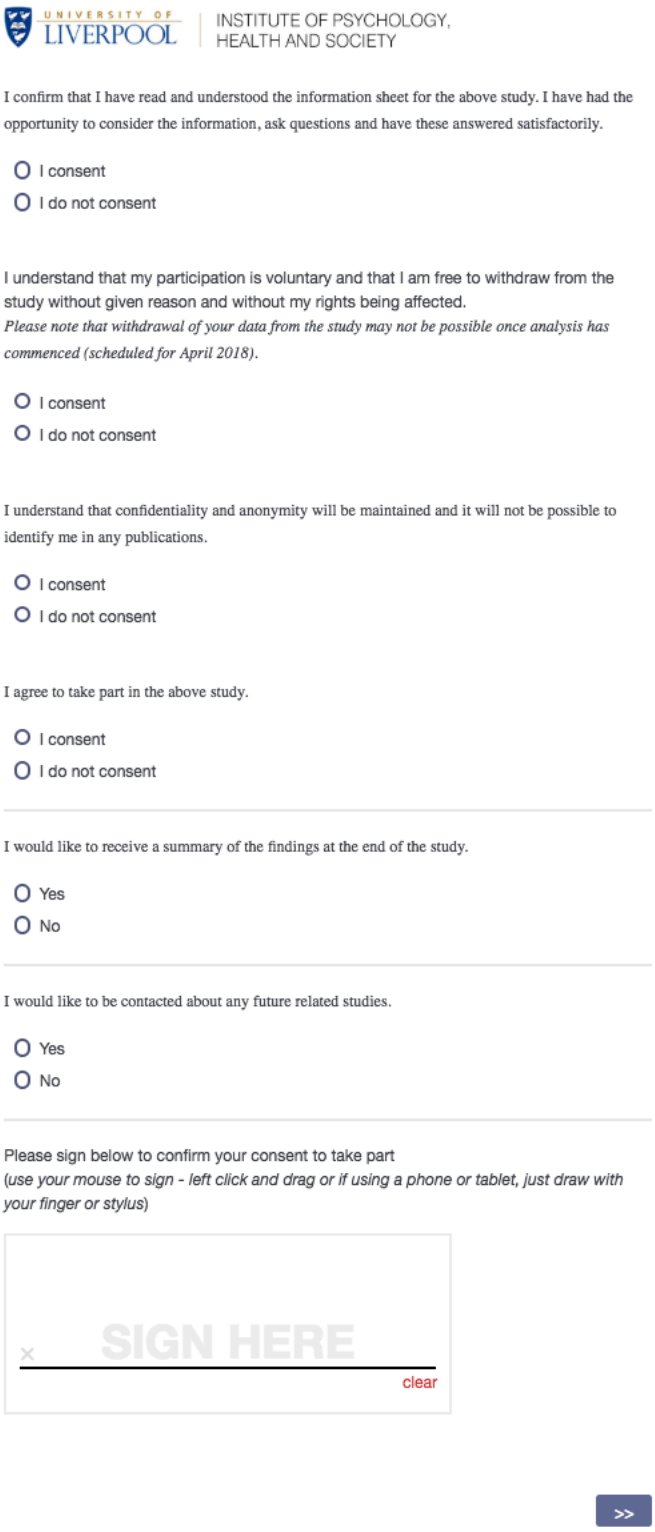
Who is the research funded by? The project is funded by the University of Liverpool as part of the Doctorate in Clinical Psychology programme.

Contact information

Miss Cerian Jackson, Doctorate in Clinical Psychology, Whelan Building, University of Liverpool, Liverpool, L69 3GB, email: Cerian.Jackson@liverpool.ac.uk

Research Support Office, University of Liverpool, Waterhouse Buildings, 3 Brownlow Street, Liverpool, L69 3GL, UK, 0151 794 2000
ethics@liverpool.ac.uk

Appendix N – Participant Consent Form (online)



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I confirm that I have read and understood the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.

- I consent
- I do not consent

I understand that my participation is voluntary and that I am free to withdraw from the study without given reason and without my rights being affected.
Please note that withdrawal of your data from the study may not be possible once analysis has commenced (scheduled for April 2018).

- I consent
- I do not consent

I understand that confidentiality and anonymity will be maintained and it will not be possible to identify me in any publications.

- I consent
- I do not consent

I agree to take part in the above study.

- I consent
- I do not consent

I would like to receive a summary of the findings at the end of the study.

- Yes
- No

I would like to be contacted about any future related studies.

- Yes
- No

Please sign below to confirm your consent to take part
(use your mouse to sign - left click and drag or if using a phone or tablet, just draw with your finger or stylus)

× SIGN HERE

clear

>>

Appendix O – Participant Consent Form (paper)

The Walton Centre NHS Foundation Trust

UNIVERSITY OF LIVERPOOL

CONSENT FORM

Research Title Investigating the impact of self-criticism and self-reassurance on the experience of distress in people with traumatic brain injuries

Once you have read and understood each statement please tick (✓) AND initial. If you do not agree, then leave blank.

	Statement	Tick	Initial
1.	I confirm that I have read and understood the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.		
2.	I understand that my participation is voluntary and that I am free to withdraw from the study without given reason and without my rights being affected. *Please note that withdrawal of your data from the study may not be possible once analysis has commenced (scheduled for April 2018)*		
3.	I understand that confidentiality and anonymity will be maintained and it will not be possible to identify me in any publications		
4.	I agree to take part in the above study		
5.	I would like to receive a summary of the findings at the end of the study.		
6.	I would like to be contacted about any future related studies.		

Contact details (needed if ticked 5 and/or 6)

Telephone number

Email address

Participant Name: Signature: Date:

_____ _____ _____

Researcher Name: Signature: Date:

_____ _____ _____

One copy to be kept by researcher, one copy to be given to the participant.

Appendix P – Questionnaire Booklet

Demographic Questionnaire

1. What is your date of birth

D D / M M / Y Y Y Y

2. Gender (please circle)
   - ☐ Male
   - ☐ Female
   - ☐ Transgender
   - ☐ Non-binary
   - ☐ Other
   - ☐ Rather not say

3. What is your highest academic attainment?
   - ☐ No qualifications
   - ☐ GCSE / O-Levels
   - ☐ HNC / HND
   - ☐ A Levels
   - ☐ Bachelor's Degree
   - ☐ Master's Degree / Post-Graduate Diploma
   - ☐ PhD / Doctorate

4. Date of injury sustained

5. How did you sustain a traumatic brain injury?
   - ☐ Road traffic accident
   - ☐ Assault
   - ☐ Military incident
   - ☐ Sports injury
   - ☐ Fall from height
   - ☐ Struck by or against an object
   - ☐ Self-inflicted
   - ☐ Other (please specify)

_____

6. Did you lose consciousness (please circle)
   - ☐ Yes
   - ☐ No

7. How long were you unconscious for? (please circle
   - ☐ Under 30 minutes
   - ☐ Between 30 minutes and 24 hours
   - ☐ Over 24 hours

8. Who do you hold responsible for the incident in which you sustained a traumatic brain injury?
   - ☐ You
   - ☐ Another person
   - ☐ No one

9. Please indicate on the scale below how much responsibility you feel in relation to the head injury? (please circle – 1 being no responsibility, 10 being most responsible)

1 2 3 4 5 6 7 8 9 10

10. Were you involved in a legal process relating to the incident in which you sustained a traumatic brain injury? (please circle)
   - ☐ Yes – completed
   - ☐ Yes – ongoing
   - ☐ No
   - ☐ Prefer not to say

11. Was anyone else injured in the incident? (please circle)
   - ☐ Yes
   - ☐ No
   - ☐ Prefer not to say

12. Were there any fatalities in the incident? (please circle)
   - ☐ Yes
   - ☐ No
   - ☐ Prefer not to say

13. Do you have epilepsy? (please circle)
   - ☐ Yes
   - ☐ No
   - ☐ Prefer not to say

14. Have you been diagnosed with any other neurological conditions? (please circle)
   - ☐ Yes
   - ☐ No
   - ☐ Prefer not to say

15. Prior to sustaining a traumatic brain injury, had you had contact with mental health services? (please circle)
   - ☐ Yes

- ☐ No
- ☐ Prefer not to say

16. Are you currently taking any medication?
    - ☐ Yes
    - ☐ No

17. What medication are you currently taking? (please list)

_____
_____
_____
_____
_____
_____

Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you over the past week. There are no right or wrong answers. Do not spend too much time on any statement.				
	Did not apply to me at all	Applied to me to some degree or some of the time	Applied to me to a considerable degree or a good part of the time	Applied to me very much or most of the time
I found it hard to wind down	1	2	3	4
I was aware of dryness in my mouth	1	2	3	4
I couldn't seem to experience any positive feeling at all	1	2	3	4
I experienced breathing difficulty (e.g. excessively rapid breathing, breathlessness in the absence of physical exertion	1	2	3	4
I found it difficult to work up the initiative to do things	1	2	3	4
I tended to over-react to situations	1	2	3	4
I experienced trembling (e,g, in the hands)	1	2	3	4
I felt that I was using a lot of nervous energy	1	2	3	4

I was worried about situations in which I might panic and make a fool of myself	1	2	3	4
I felt that I had nothing to look forward to	1	2	3	4
I found myself getting agitated	1	2	3	4
I found it difficult to relax	1	2	3	4
I felt down-hearted and blue	1	2	3	4
I was intolerant of anything that kept me from getting on with what I was doing	1	2	3	4
I felt I was close to panic	1	2	3	4
I was unable to become enthusiastic about anything	1	2	3	4
I felt I wasn't worth much as a person	1	2	3	4
I felt that I was rather touchy	1	2	3	4
I was aware of the action of my heart in the absence of physical exertion (e.g. sense of heart rate increase, heart missing a beat)	1	2	3	4
I felt scared without any good reason	1	2	3	4
I felt life was meaningless	1	2	3	4

These questions are about your thinking abilities now (including the past week)					
	Not at all	Slightly	Moderately	Quite	Very
How satisfied are you with your ability to concentrate for example when reading or keeping track of conversations?	1	2	3	4	5
How satisfied are you with your ability to express yourself and understand others in a conversation?	1	2	3	4	5

How satisfied are you with your ability to remember everyday things, for example where you have put things?	1	2	3	4	5
How satisfied are you with your ability to plan and work out solutions to everyday practical problems, for example what to do when you lose your keys?	1	2	3	4	5
How satisfied are you with your ability to make decisions?	1	2	3	4	5
How satisfied are you with your ability to find your way around?	1	2	3	4	5
How satisfied are you with your speed of thinking?	1	2	3	4	5

Please select the degree to which you disagree or agree with the following statements. This refers to your usual way of life within the last week.							
	Strongly agree						Strongly Disagree
My motivation is lower when I am fatigued	1	2	3	4	5	6	7
Exercise brings on my fatigue	1	2	3	4	5	6	7
I am easily fatigued	1	2	3	4	5	6	7
Fatigue interferes with my physical functioning	1	2	3	4	5	6	7
Fatigue causes frequent problems for me	1	2	3	4	5	6	7
My fatigue prevents sustained physical functioning	1	2	3	4	5	6	7
Fatigue interferes with carrying out certain duties and responsibilities	1	2	3	4	5	6	7
Fatigue is among my most disabling symptoms	1	2	3	4	5	6	7
Fatigue interferes with my work, family or social life	1	2	3	4	5	6	7

Please rate your pain by marking the number that best describes your pain at its worst in the last 24 hours.											
	No pain										Pain as bad as you can imagine
Please rate your pain by marking the number that best describes your pain at its *worst* in the last 24 hours	0	1	2	3	4	5	6	7	8	9	10
Please rate your pain by marking the number that best describes your pain at its *best* in the last 24 hours	0	1	2	3	4	5	6	7	8	9	10
Please rate your pain by marking the number that best describes your pain on *average*	0	1	2	3	4	5	6	7	8	9	10
Please rate your pain by marking the number that tells how much pain you have right now	0	1	2	3	4	5	6	7	8	9	10

Mark the number that describes how much, during the past 24 hours, pain has interfered with your:											
	Does not interfere										Completely interferes
General Activity	0	1	2	3	4	5	6	7	8	9	10
Mood	0	1	2	3	4	5	6	7	8	9	10
Walking Ability	0	1	2	3	4	5	6	7	8	9	10
Normal Work (includes both work outside the home and housework)	0	1	2	3	4	5	6	7	8	9	10
Relations with other people	0	1	2	3	4	5	6	7	8	9	10
Sleep	0	1	2	3	4	5	6	7	8	9	10
Enjoyment of life	0	1	2	3	4	5	6	7	8	9	10

Below are listed some examples of things that happen to people in every day life. Some of them may happen frequently and some may happen very rarely. We should life to know how often on average you think each has happened to you over the past month					
	Once or less in the last month	More than once a month but less than once a week	About once a week	More than once a week but less than once a day	Once or more in a day
Having to check whether you have done something that you should have done?	1	2	3	4	5
Forgetting when it was that something happened; for example, whether it was yesterday or last week	1	2	3	4	5
Forgetting that you were told something yesterday or a few days ago, and maybe having to be reminded about it	1	2	3	4	5
Starting to read something (a book or an article in a newspaper, or a magazine) without realising you have already read it before	1	2	3	4	5
Finding that a word is ‘on the tip of your tongue’. You know what it is but cannot quite find it.	1	2	3	4	5
Completely forgetting to do things you said you would do, and things you planned to do	1	2	3	4	5
Forgetting important details of what you did or what happened to you the day before	1	2	3	4	5
When talking to someone forgetting what you have just said. Maybe saying 'what was I talking about?'	1	2	3	4	5
When reading a newspaper or magazine, being unable to follow the thread of a story; losing track of what it is about	1	2	3	4	5
Forgetting to tell somebody something important, perhaps forgetting to pass on a message or remind someone of something	1	2	3	4	5
Getting the details of what someone had told you mixed up and confused	1	2	3	4	5
Forgetting where things are normally kept or looking for them in the wrong place	1	2	3	4	5

Repeating to someone what you have just told them or asking someone the same question twice	1	2	3	4	5

Below you will find a list of statements. Please rate how true each statement is for you.

When I have a critical thought about myself....

	Never true	Very seldom true	Seldom true	Sometimes true	Frequently true	Almost always true	Always true
... it makes me lose control of my behaviour	1	2	3	4	5	6	7
... I do things I later regret	1	2	3	4	5	6	7
... I try to ignore it*	1	2	3	4	5	6	7
... I feel so ashamed that I don't act the way I should	1	2	3	4	5	6	7
... I feel so disgusted at myself that I don't act the way I should	1	2	3	4	5	6	7
... I try not to think about it*	1	2	3	4	5	6	7
... I don't treat myself the way I would like	1	2	3	4	5	6	7
... I pretend it's not there*	1	2	3	4	5	6	7
... I don't treat others the way I should	1	2	3	4	5	6	7
... I act in a way that makes life more difficult for me	1	2	3	4	5	6	7
... I try to block out any feelings it creates*	1	2	3	4	5	6	7
... It gets me so down that I don't act the way I should	1	2	3	4	5	6	7

When things go wrong in our lives or don't work out as we hoped, and we feel we could have done better, we sometimes have *negative and self-critical thoughts and feelings*. These may take the form of feeling worthless, useless or inferior etc. However, people can also try to be supportive of themselves. Below are a series of thoughts and feelings that people sometimes have. Read each statement carefully and circle the number that best describes how much each statement is true for you.					
	Not at all like me	A little bit like me	Moderately like me	Quite a bit like me	Extremely like me
I am easily disappointed with myself	1	2	3	4	5
There is a part of me that puts me down	1	2	3	4	5
I am able to remind myself of positive things about myself	1	2	3	4	5
I find it difficult to control my anger	1	2	3	4	5
I find it easy to forgive myself	1	2	3	4	5
There is a part of me that feels I am not good enough	1	2	3	4	5
I feel beaten down by my own self-critical thoughts	1	2	3	4	5
I still like being me	1	2	3	4	5
I have become so angry with myself that I want to hurt or injure myself	1	2	3	4	5
I have a sense of disgust with myself	1	2	3	4	5
I can still feel lovable and acceptable	1	2	3	4	5
I stop caring about myself	1	2	3	4	5
I find it easy to like myself	1	2	3	4	5
I remember and dwell on my failings	1	2	3	4	5
I call myself names	1	2	3	4	5

I am gentle and supportive with myself	1	2	3	4	5
I can't accept failure and setbacks without feeling inadequate	1	2	3	4	5
I think I deserve my self-criticism	1	2	3	4	5
I am able to care and look after myself	1	2	3	4	5
There is a part of me that wants to get rid of the bits I don't like	1	2	3	4	5
I encourage myself for the future	1	2	3	4	5
I do not like being me	1	2	3	4	5

These questions are about your emotions and view of yourself now (including the past week)					
	Not at all	Slightly	Moderately	Quite	Very
How satisfied are you with your level of energy?	1	2	3	4	5
How satisfied are you with your level of motivation to do things?	1	2	3	4	5
How satisfied are you with your self-esteem, how valuable you feel?	1	2	3	4	5
How satisfied are you with the way you look?	1	2	3	4	5
How satisfied are you with what you have achieved since your brain injury?	1	2	3	4	5
How satisfied are you with the way you perceive yourself?	1	2	3	4	5
How satisfied are you with the way you see your future?	1	2	3	4	5

These questions are about how bothered you are by physical problems now (including the past week)					
	Not at all	Slightly	Moderately	Quite	Very
How bothered are you by slowness and/or clumsiness of movement?	1	2	3	4	5
How bothered are you by effects of any other injuries you sustained at the same time as your brain injury?	1	2	3	4	5
How bothered are you by pain, including headaches?	1	2	3	4	5
How bothered are you by problems with seeing or hearing?	1	2	3	4	5

Overall, how bothered are you by the effects of your brain injury?	1	2	3	4	5

These questions are about how bothered you are by your feelings (including the past week)					
	Not at all	Slightly	Moderately	Quite	Very
How bothered are you by feeling lonely, even when you are with other people?	1	2	3	4	5
How bothered are you by feeling bored?	1	2	3	4	5
How bothered are you by feeling anxious?	1	2	3	4	5
How bothered are you by feeling sad or depressed?	1	2	3	4	5
How bothered are you by feeling angry or aggressive?	1	2	3	4	5

These questions are about your social relationships now (including the past week)					
	Not at all	Slightly	Moderately	Quite	Very
How satisfied are you with your ability to feel affection towards others, for example your partner, family, friends?	1	2	3	4	5
How satisfied are you with your relationships with members of your family?	1	2	3	4	5
How satisfied are you with your relationships with your friends?	1	2	3	4	5
How satisfied are you with your relationship with a partner or with not having a partner?	1	2	3	4	5
How satisfied are you with your sex life?	1	2	3	4	5
How satisfied are you with the attitudes of other people towards you?	1	2	3	4	5

These questions are about your independence and how you function in daily life now (including the past week).					
	Not at all	Slightly	Moderately	Quite	Very
How satisfied are you with the extent of your independence from others?	1	2	3	4	5
How satisfied are you with your ability to get out and about?	1	2	3	4	5
How satisfied are you with your ability to carry out domestic activities, for example cooking or repairing things?	1	2	3	4	5

How satisfied are you with your ability to run your personal finances?	1	2	3	4	5
How satisfied are you with your participation in work or education?	1	2	3	4	5
How satisfied are you with your participation in social and leisure activities, for example sports, hobbies, parties?	1	2	3	4	5
How satisfied are you with the extent to which you are in charge of your own life?	1	2	3	4	5

Appendix Q – Link to Online Questionnaire Preview

https://eu.qualtrics.com/jfe/preview/SV_0wXybjIBa143Zn7?Q_SurveyVersionID=current&Q_CHL=preview

Appendix R – Exploration of Normality and Parametric Assumptions

Table R1. Test of Normality Table

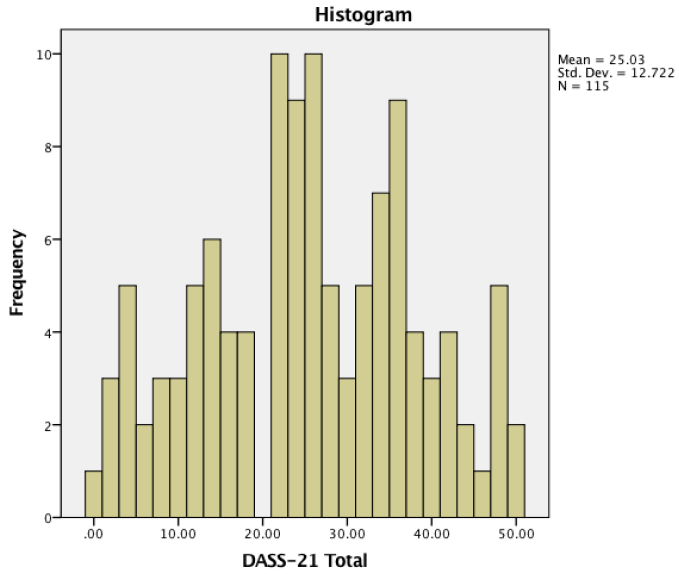

Figure R1. Histogram of DASS-21 (total) distribution

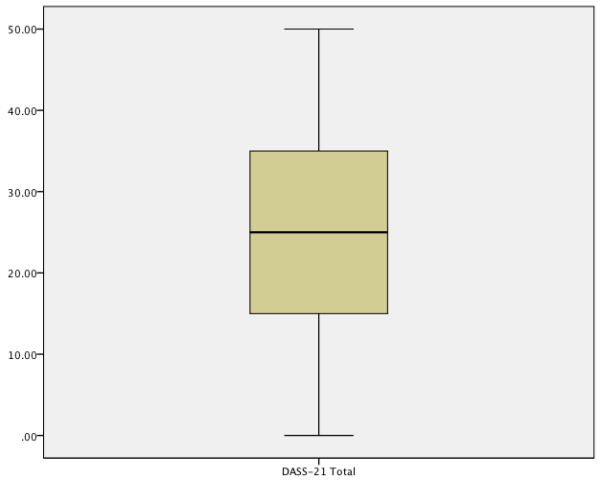

Figure R2. DASS-21 Box Plot

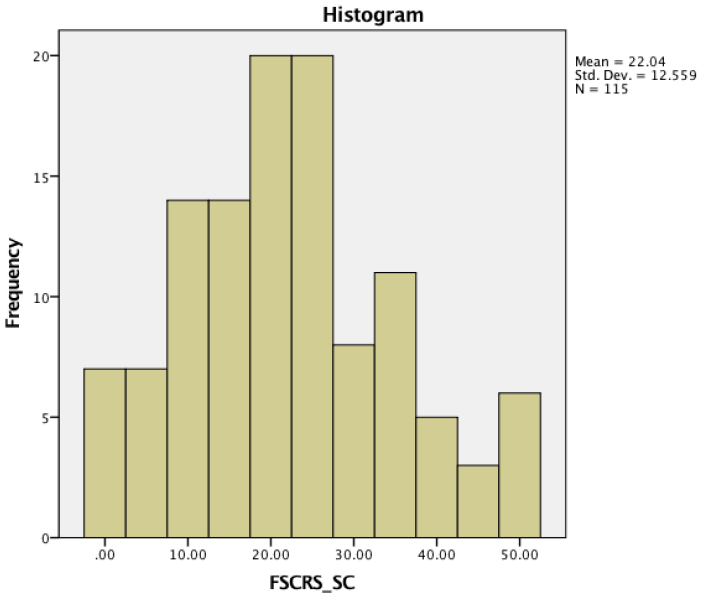

Figure R3. Histogram of FSCRS (Self-Criticism) distribution

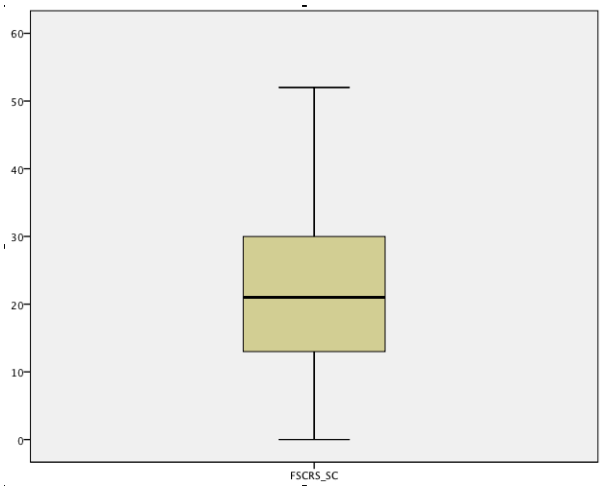

Figure R4. FSCSR (Self-Criticism) Box Plot

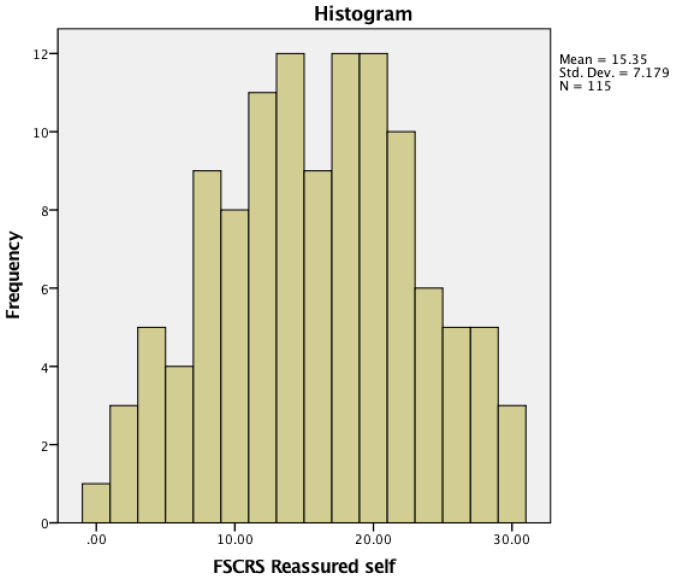

Figure R5. Histogram of FSCRS (Reassured) distribution

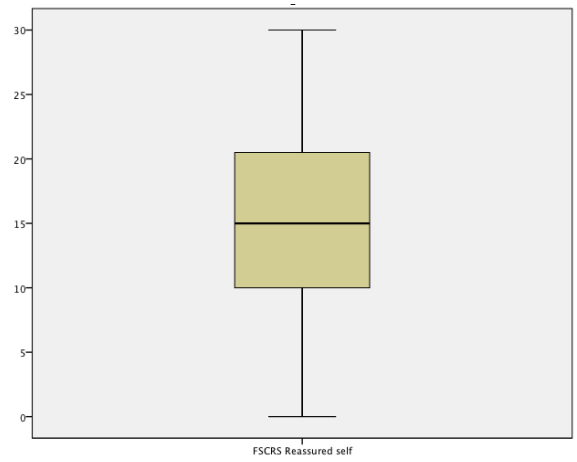

Figure R6. FSCSR (Reassured) Box Plot

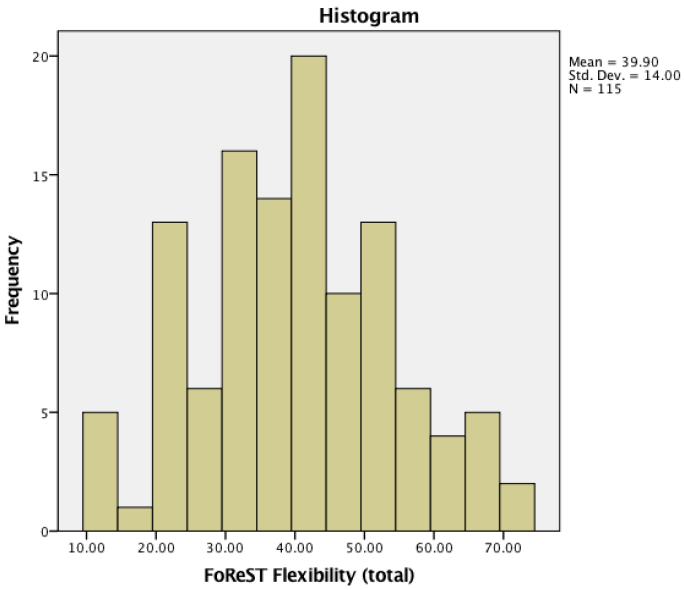

Figure R9. Histogram of FoReST (Flexibility) distribution

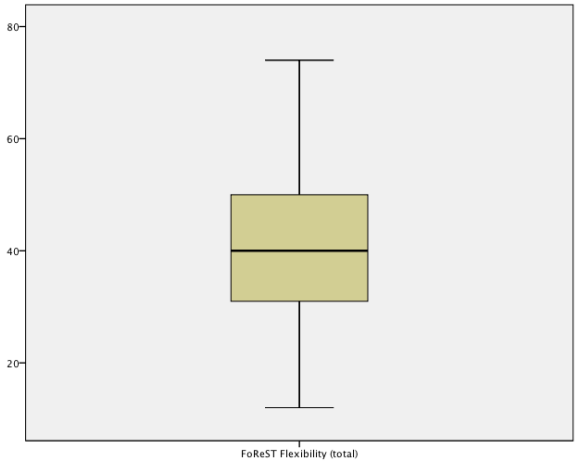

Figure R10. FoReST (Flexibility) Box Plot

Exploration of regression assumptions

Independence of residuals

Durbin-Watson statistic was 2.167 and therefore did not indicate that residuals were not independent.

Linear relationship between the dependent variable and each of the independent variables and a linear relationship between the dependent variable and the independent variables collectively.

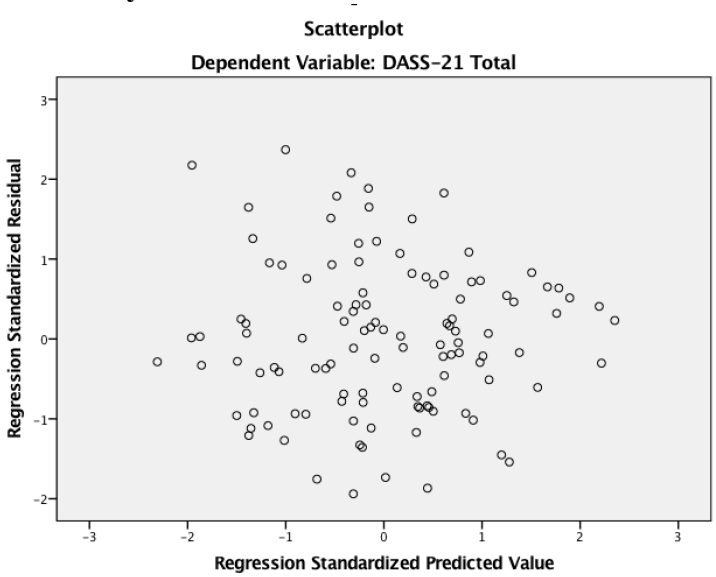

Figure R10. Scatter plot of regression standardised residuals vs regression standardised predicted value.

Assessed visually and no evidence of non-linearity identified.

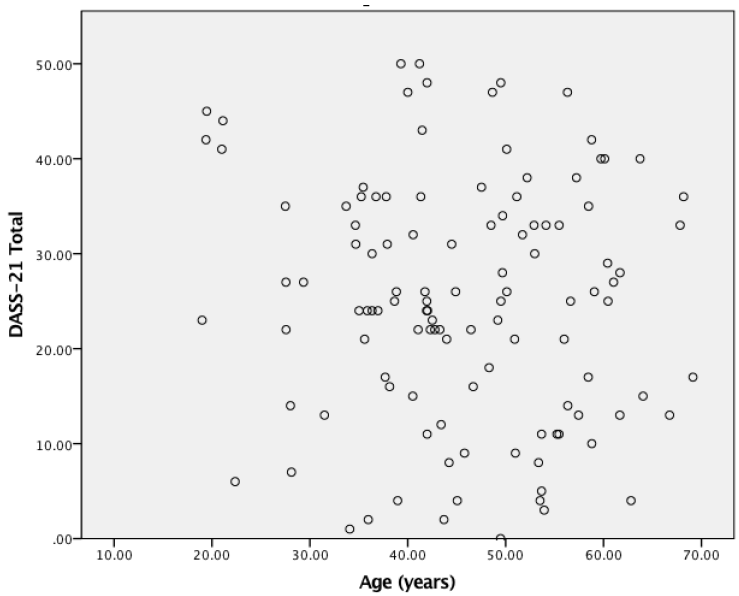

Figure R11. Scatter plot of age vs DASS-21

Assessed visually and no evidence of non-linearity identified.

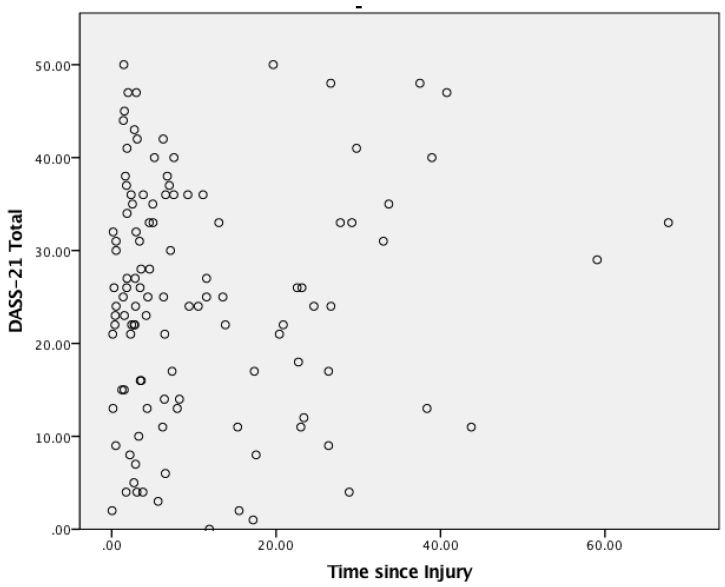

Figure R12. Scatter plot of time since injury vs DASS-21

Assessed visually and no evidence of non-linearity identified.

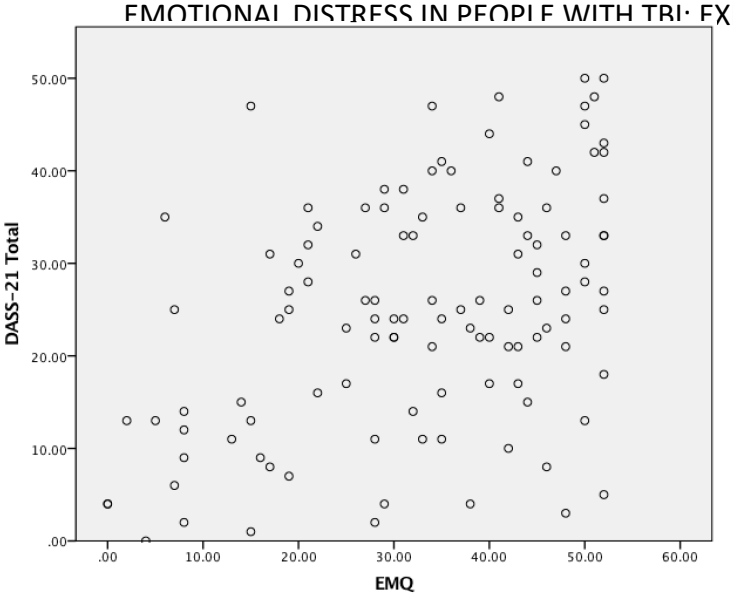

Figure R13. Scatter plot of EMQ vs DASS-21

Assessed visually and no evidence of non-linearity identified.

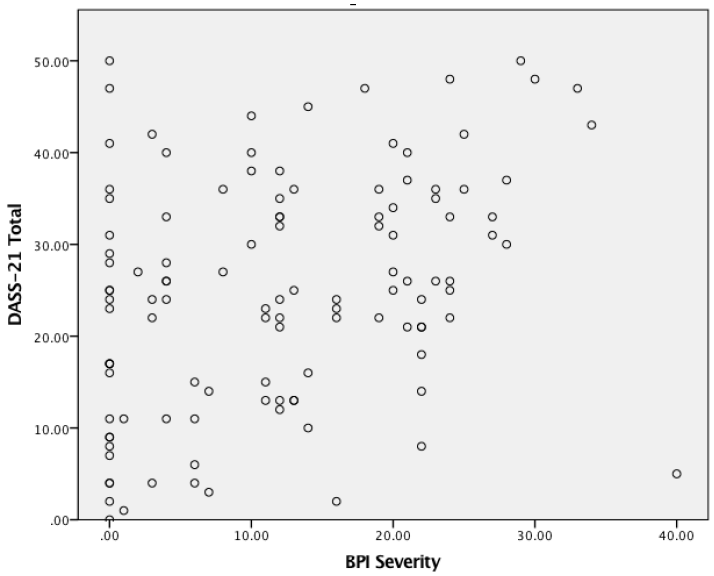

Figure R14. Scatter plot of BPI Severity vs DASS-21

Assessed visually and no evidence of non-linearity identified.

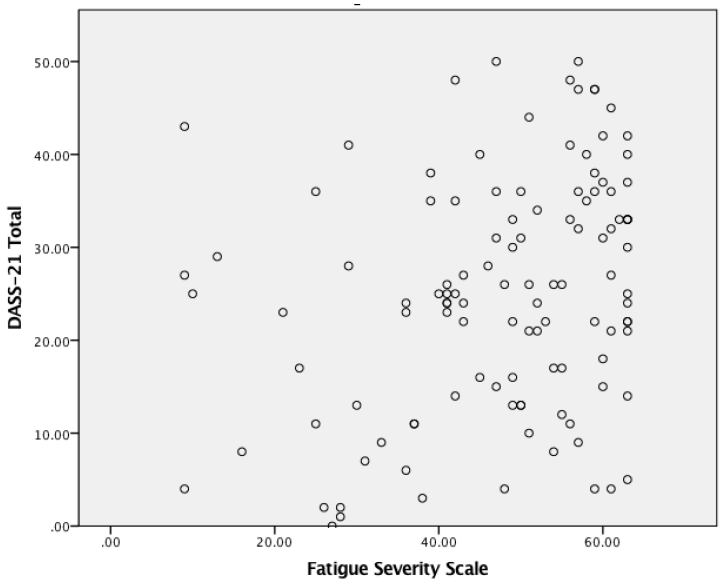

Figure R15. Scatter plot of FSS vs DASS-21

Assessed visually and no evidence of non-linearity identified.

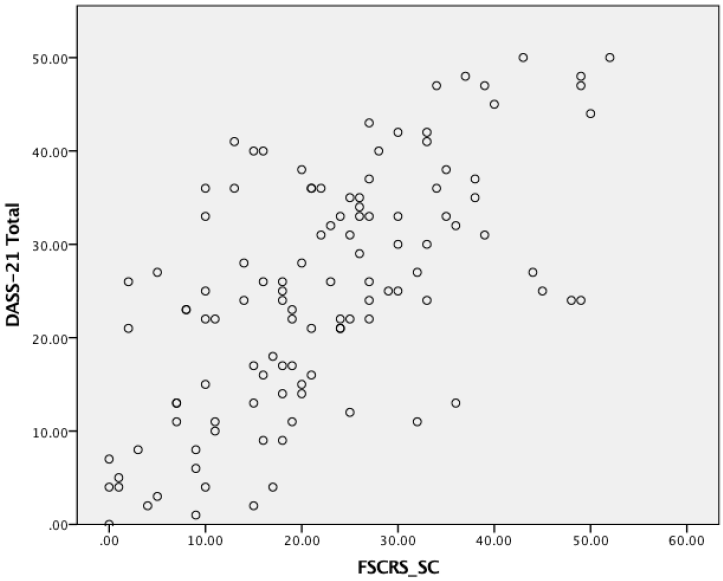

Figure R16. Scatter plot of FSCRS Self-Criticism vs DASS-21

Assessed visually and no evidence of non-linearity identified.

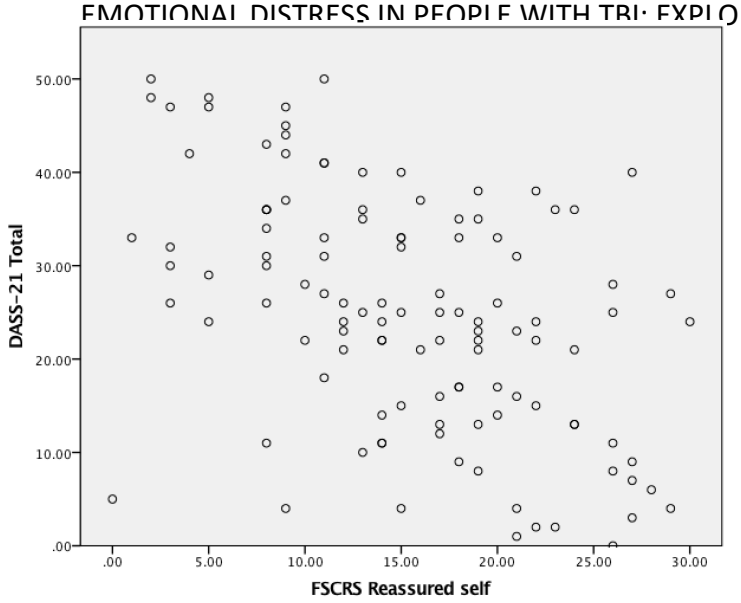

Figure R18. Scatter plot of FSCRS Reassured self vs DASS-21

Assessed visually and no evidence of non-linearity identified.

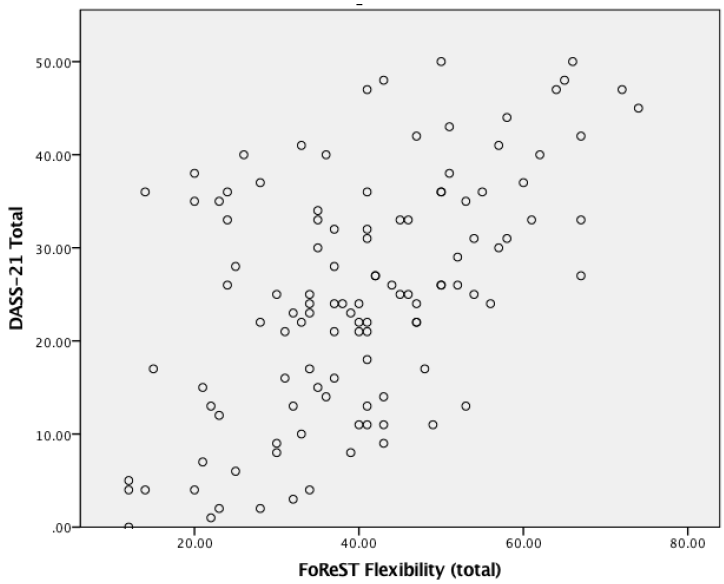

Figure R19. Scatter plot of FoReST Flexibility vs DASS-21

Assessed visually and no evidence of non-linearity identified.

Homoscedasticity of residuals

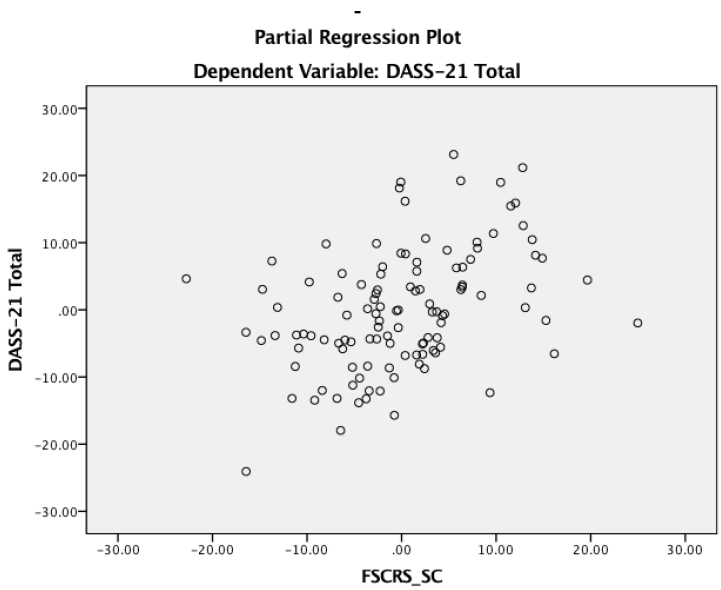

Figure R20. Scatter plot of Unstandardised Predicted Values vs Studentized Residuals

Evidence of homoscedasticity identified as assessed visually.

Multicollinearity

It was noted that for the gender and psychiatric history variables, which were dummy coded into dichotomous variables, the variance inflation factors (VIFs) were below 0.1 and tolerance values were greater than 10. Therefore in the analysis, Psychiatric history: no (vs Psychiatric history: yes and prefer not to say) was removed from the analysis. This decision was made as psychiatric history has been indicated as a risk factor for poor psychological outcomes in people with TBI. Similarly, Gender: male (vs female and nonbinary) was removed from the regression. Again, as female gender has been indicated as a risk factor for poor psychological outcomes following TBI in previous research. The remaining VIFs and tolerance values were below 0.1 and 10, respectively and did not indicate evidence for multicollinearity.

No significant outlier, high leverage points or highly influential points

Casewise diagnostics table was did not appear in the regression output which indicates that all standardised residuals were <±3.

There were no Cook's values above 1.

Residuals are approximately normally distributed

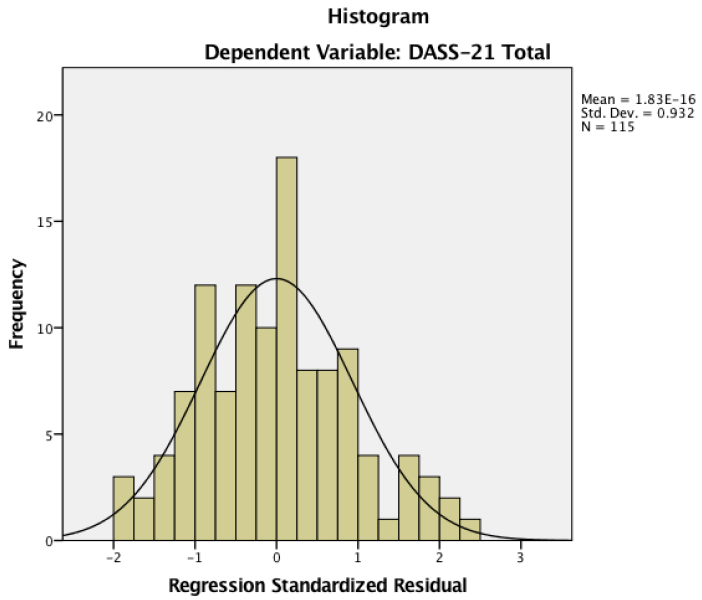

Figure R21. Histogram of Regression Standardised Residuals

Normal distribution identified as assessed visually.

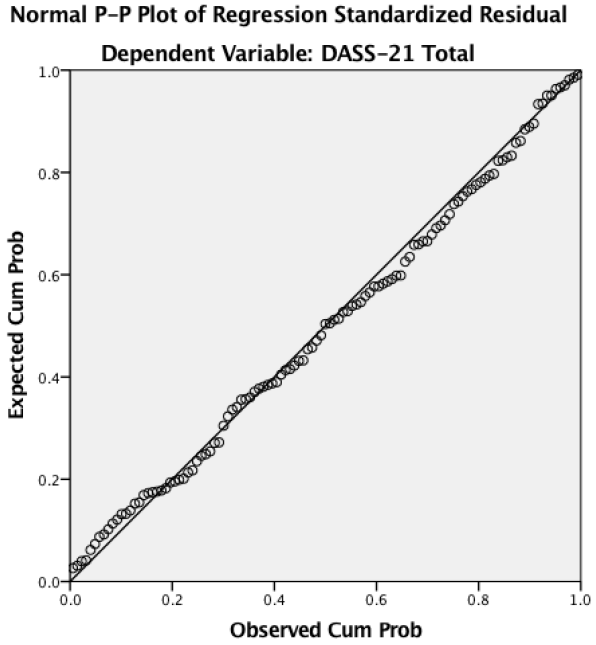

Figure R22. P-P Plot of Regression Standardized Residuals.

Normal distribution identified as assessed visually.

Appendix S – Email to authors of included studies to request protocol and further information where required:

Dear Professor Elgmark Andersson,

I am currently completing a systematic review titled:

Early Psychological Interventions for the Prevention of Persistent Postconcussion Symptoms Following Mild Traumatic Brain Injury

Your published research (citation below) has been identified as meeting all inclusion criteria.

Andersson, E. E., Emanuelson, I., Björklund, R., & Stålhammar, D. A. (2007). Mild traumatic brain injuries: the impact of early intervention on late sequelae. A randomized controlled trial. *Acta neurochirurgica*, *149*(2), 151-160.

and

Andersson, E. E., Bedics, B. K., & Falkmer, T. (2011). Mild traumatic brain injuries: a 10-year follow-up. *Journal of rehabilitation medicine*, *43*(4), 323-329.

As part of the review process, I am writing to request the protocol (if available) for the above project and to request the summary data (means and standard deviations) for the New Swedish Post Concussion Questionnaire and SF-36 (overall) outcomes at baseline and follow up for both the treated and nontreated groups.

Thanks in anticipation and I look forward to hearing from you soon.

Cerian Jackson
Trainee Clinical Psychologist
University of Liverpool

Under the supervision of:
Dr Perry Moore
Consultant Clinical Neuropsychologist
The Walton Centre NHS Foundation Trust

Dr Ross White
Research Director – DClinPsy Programme
University of Liverpool

Appendix T – Risk of Bias of Included Studies

Author	Random Sequence	Allocation Concealment	Outcome Assessor Blinding	Incomplete Outcome Data	Selective Outcome Reporting	Other
Andersson 2007[25]	Low Minimisation method (Pocock & Simon, 1975)	Unclear No mention of allocation concealment	Low Questionnaires were mailed to participants and data was inputted by secretaries who were unaware of group assignment.	Low Drop outs comparable across the groups	High Although all outcomes discussed were reported, incomplete summary data was reported	None identified
Ghaffar 2006[26]	Unclear No details of how randomisation was achieved	Unclear No details of attempts to conceal allocation	Unclear No details of attempts to blind outcome assessors	High Drop outs reported but inconsistency noted between this and the numbers included in the analysis	Low All outcomes discussed were reported	None identified
Matuseviciene 2013[27]	Unclear No details of how	Unclear No details of attempts to	Unclear No details of attempts to	Low Drop outs were reported	High Incomplete summary	None identified

	randomisation was achieved	conceal allocation	blind outcome assessors	and comparable across the groups	data was reported	
Mittenberg 1996[28]	Unclear No details of how randomisation was achieved	Unclear No details of attempts to conceal allocation	Low Follow up assessor was not aware of group assignment	Unclear No details regarding drop out rates	Low All outcomes described were reported	Baselines measurements were completed retrospectively
Scheenen 2017[29]	Unclear No details of how randomisation was achieved	Unclear No details of attempts to conceal allocation	Low Follow up assessor was not aware of group assignment	Low Drop outs were reported and were comparable across the groups	Low All outcomes described were reported	None identified
Silverberg 2013[30]	Low Web-based random number generator was used	Low Allocation was concealed prior to participants being recruited	Unclear Although states outcome assessors were blinded, no information about how this was achieved	Low Drop outs were reported and were comparable across the groups	Low All outcomes described were reported	None identified
Suffoletto 2013[31]	Low Random computer generated list produced	Unclear Although states that investigator was unaware of random	Unclear Although states assessors were blinded, it is unclear how this	Low Drop outs were reported and were comparable across the groups	Low Outcomes discussed were reported	None identified

		sequence, it is unclear how this was achieved	was achieved			
Wade 1997[32]	Low Random computer generated list produced	Unclear No details of attempts to conceal allocation	Low Follow up assessor was not aware of group assignment	Low Assessors were clinicians who had not been involved in the trial and were unaware of group assignment	Unclear Outcomes discussed were reported	Not identified
Wade 1998[33]	Low Random computer generated list produced, with a preference for trial participants 1.5:1	Unclear No details of attempts to conceal allocation	Low Follow up assessor was not aware of group assignment	Low Assessors were independent and unaware of group assignment	Unclear Outcomes discussed were reported	Not identified

Appendix U – PRISMA Diagram Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	10
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	10
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	10-13
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	12-13
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	13
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	13
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	15
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	15
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	15
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	15-16
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	16
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	16
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	17
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	17

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	16
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	n/a
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	17
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	18-26
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	31-32
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	27-31
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	27-31
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	n/a
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	n/a
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	33-34
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	36-37
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	39
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	39